ISSUE No. 60

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2023

Delvin Formulations

Destiny for Innovation

MOVING GLOBALLY

R & D and Manufacturing of API

R & D and Manufacturing of Formulations

International Marketing

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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EDITORIAL

Dear Readers,

We are happy to publish the 60th issue of Pharma Web Newsletter for Oct – Dec 2023.

This 60th issue contains the program highlights as well as the following articles published by eminent person in Pharma industry.

- **Building Product Robustness in Product Lifecycle** by
  Mr. Sajay Sharma Senior Vice President & Head, Manufacturing Science and Technology, Zydus Group

We have also published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules, important circulars issued by DCGI pertaining to Drugs & Pharmaceuticals.

Important news items connected to our Pharmacy profession appeared in various national newspapers relevant to our Pharmacy profession are published

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,

R. NARAYANASWAMY

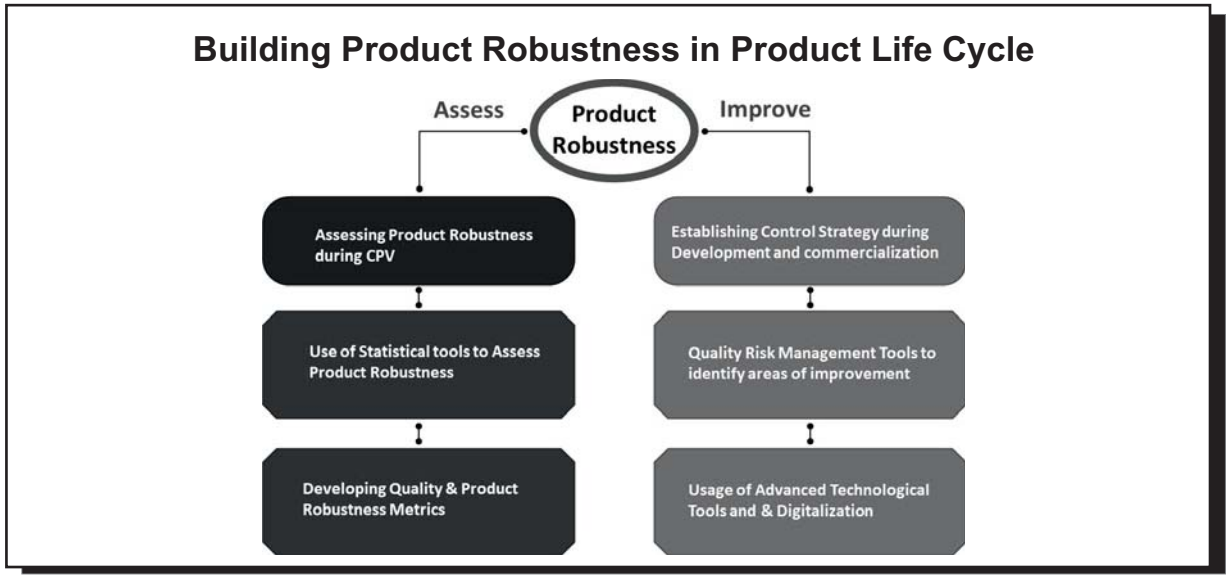
Chief Editor

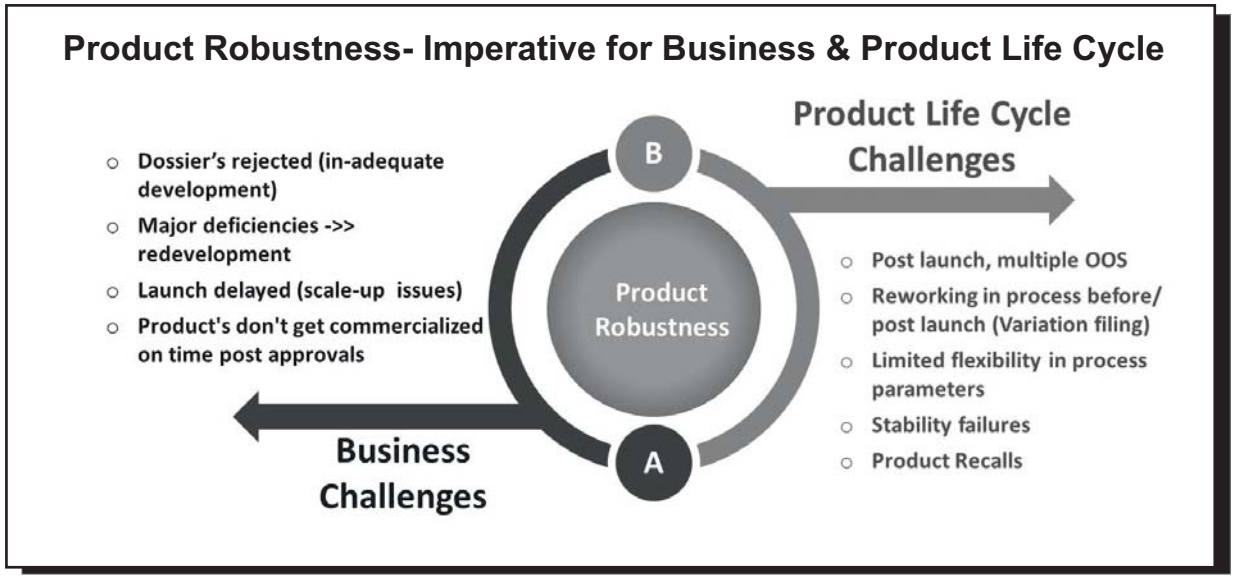
ARTICLES

Building Product Robustness in Product Lifecycle

by
Mr. Sajay Sharma
Senior Vice President & Head, Manufacturing Science and Technology, Zydus Group

Lecture Delivered during Pharmexcil Seminar held on 2nd February 2024 in Indore





Assessing Product Robustness during CPV
Continued Process Verification – "CPV"

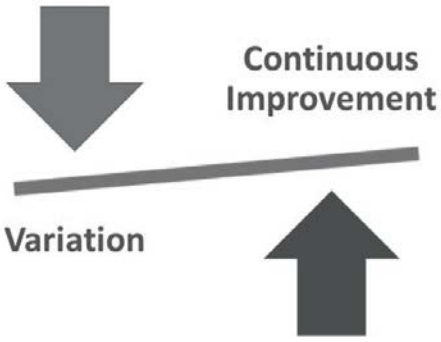
CPV is a formal procedure which enables detection of a variation in the manufacturing process that might have impact on the product quality / process consistency

CPV should:

- Evaluate that a Process continues to operate robustly within the validated state
- Identify any new sources of variability since the stage 2 (PQ stage) was performed

CPV Scope:

- With limited data when commercial production starts, CPV analysis should be performed in two phases:
  - **CPV Phase 1-** *Pre-SPC*
  - **CPV Phase 2-** *SPC Phase*

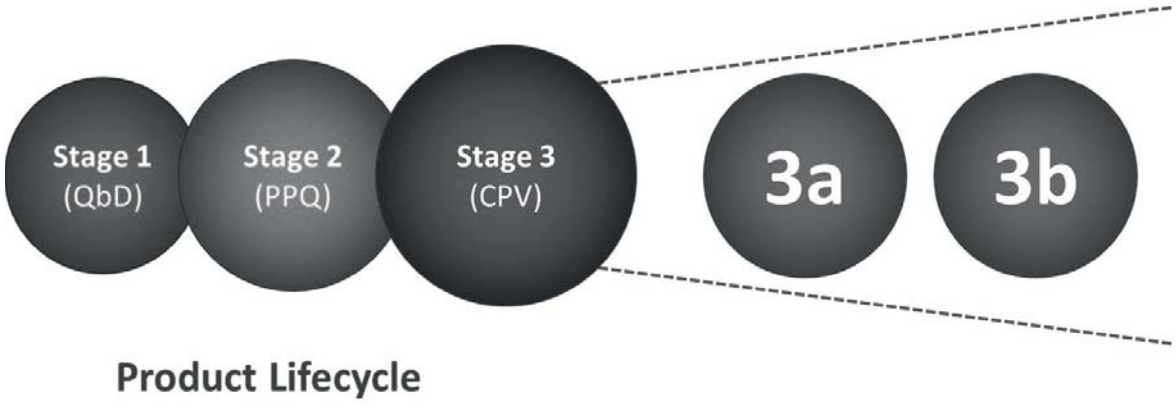


Continued Process Verification – "CPV" Current State

- Control Strategy for products done during initial Product development.
- However, during product lifecycle it goes through many changes:
  - Equipment
  - Scale
  - API/RM/PM
  - Environment conditions
  - GMP/ System related, Etc.
- Difficult to foresee these variations during the development phase.

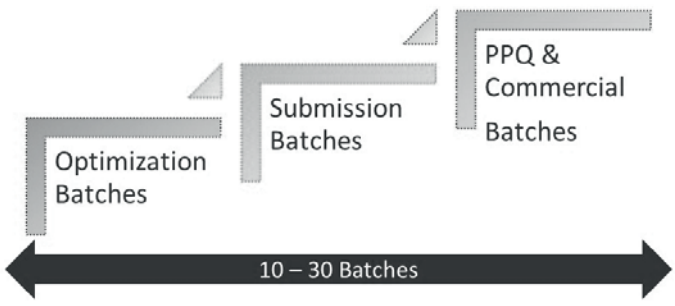
- It's also important to refine the control strategy that comes out of development and to enhance it into one that can be executed in manufacturing.
- A false perception that the annual product quality review (APQR) replaces Stage 3 is still prevalent across the industry, and it should be recognized that, unlike the APQR, the CPV program requires a system for detecting drifts promptly.

Continued Process Verification – "CPV" Stages



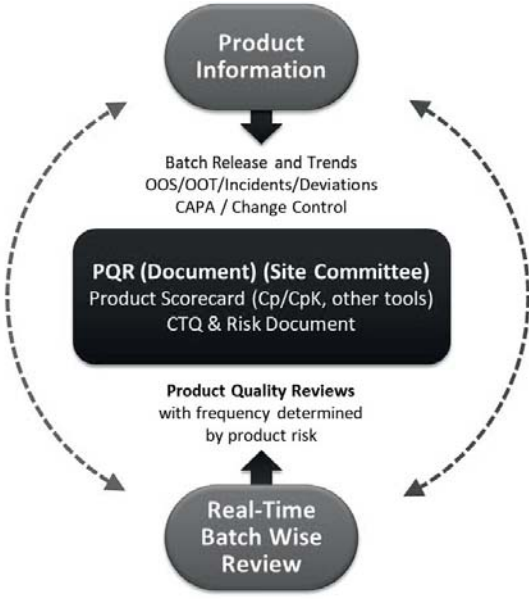
Continued Process Verification – "CPV" Phase 1 Pre-SPC

- Process performance analysed on limited data set (including PPQ, Submission & Optimization batches)
- Post Phase 1:
  - Implement alert limits
  - Relook at risk assessment
  - Evaluate new parameters



Continued Process Verification – "CPV" Phase 2 SPC

- Ongoing verification (product lifetime)
- Identify trends (potential to drift outside alert limit)



Continued Process Verification – Elements & Deliverables

3 Key Elements®

- Application of **Statistics** (MVDA) and Data Trending.
- **Risk Assessment Tools** to Evaluate impact of changes in CPP, CMA on CQA.
- Utilization of **Advanced Tools** (PAT, AI, ML) for in-built process controls.

Key Deliverables

- **Quality Metrics** as per Regulatory Expectations
- **Dynamic APQR** in conjunction with CPV reports
- **Statistical report** to identify process drifts for timely decision making
- **Online process control** to avoid End failures (Golden batch, Golden tunnel)

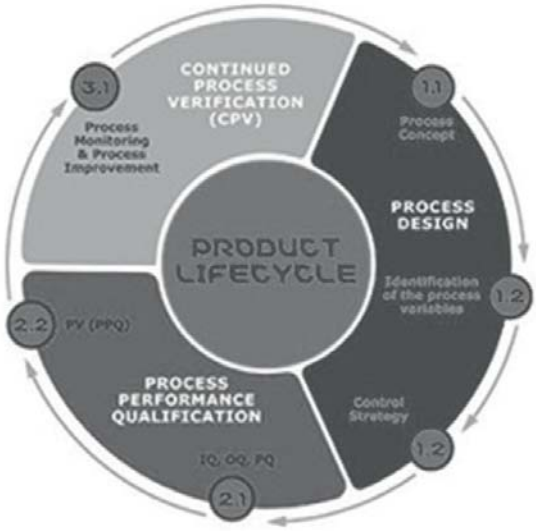
Use of Statistical tools to Assess Product Robustness
Statistics in Product Lifecycle

Tools to trend and evaluate data

- **New products** – continue from FMEA (Conducted during Stage 1, updated after Stage 2)
- **Legacy** – should not be limited to the past
- **Statistical approaches** (ICH Q9) – DOE, Histograms, Pareto charts, Control charts, process capability

CPV reporting

- Control alerts defined in CPV plan
- Calculations of process capability, SPC charts, control limits and alerts



SPC & SQC – A Roadmap

Data Acquisition

- Acquire from different sources – Manual, Online data including from ERP, LIMS, e-BPRs, Analytical data etc.

"Garbage in – Garbage out"

Data Preparation

- Identification of Continuous, Discrete Data
- Identification of Outliers
  - Parametric
  - Non-Parametric Analysis

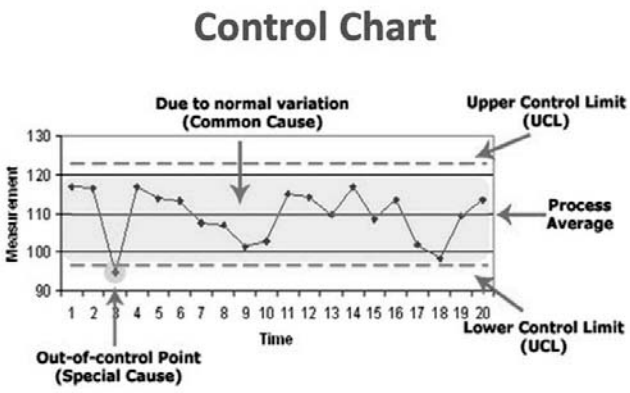
-Histograms
-Scatter & Probability plot

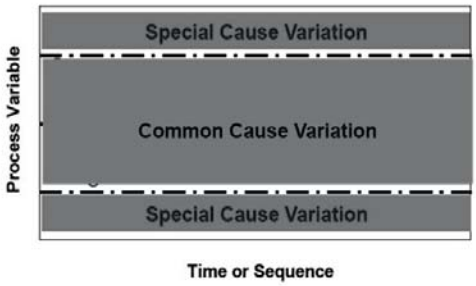
Data Analysis

- Basic Statistics
- Checking Data Distribution
- Data transformation (if necessary)
- Plotting Control Charts
- Run tests
- Process Capability Analysis

Control Charts & Process Capability Estimation

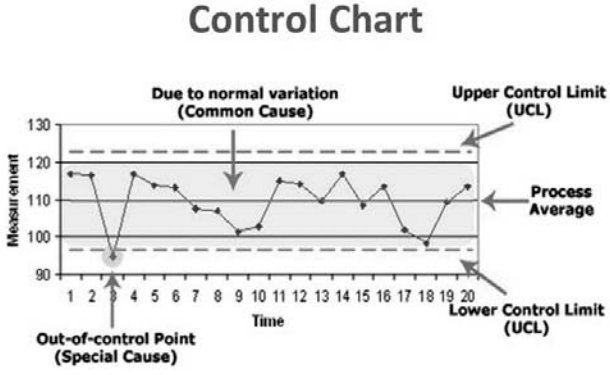
Process/Product Variation – Process Performance

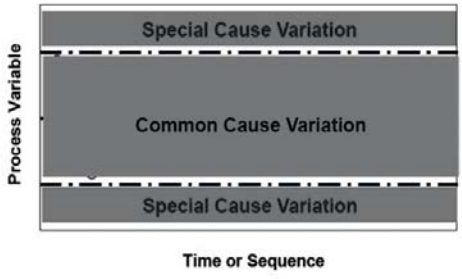




- **Set of data** (CQA, CMA, CPP)
- **Central line** (mean)
- Two statistical process **control limits**
- Upper & lower **specification limit**

Process/Product Variation – Process Performance



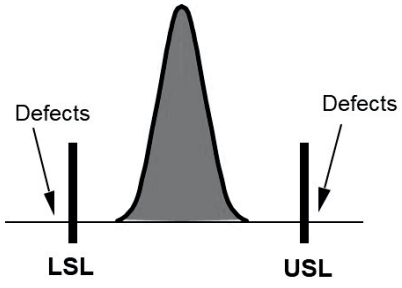


Potential Applications

1. Proactively monitor and trend a process
2. Detect presence of special cause variation
3. Identify continual improvement opps
4. Maintain process within statistical control

Process/Product Variation – Process Performance

- Process capability is the ability of the process to meet the design specifications for a service or product.
- Nominal value is a target for design specifications.
- Tolerance is an allowance above or below the nominal value.

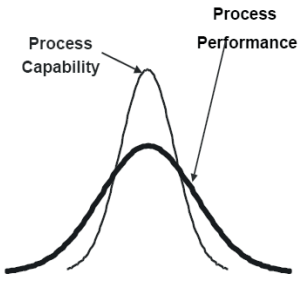


Centering – The Process is on Target

Spread – Reduce the Variation

Process/Product Variation – Process Performance

- **Process Capability** is the variation the process would exhibit if only common cause variation were present
- **Process Performance** is the total variation experienced by the customer; includes common cause, and special cause variation



Two traditional measures of process performance:

$$Pp = \frac{USL - LSL}{6\ (Long\text{-}term\ \text{Standard Deviation})}$$

Where:

LSL = Lower Specification Limit

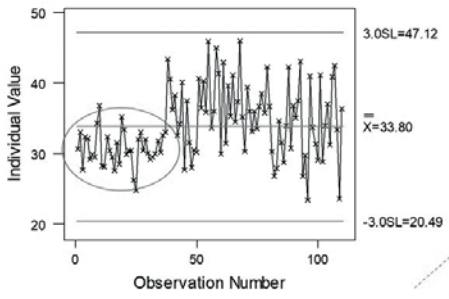
USL = Upper Specification Limit

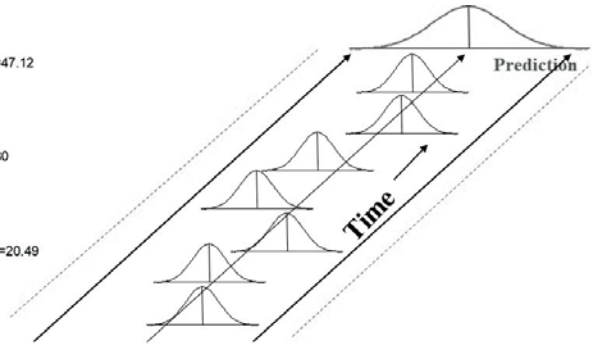
$$Ppk = \frac{\text{Min (USL – Average, Average – LSL)}}{3\ (Long\text{-}term\ \text{Standard Deviation})}$$

Process/Product Variation – "Process Capability" vs "Performance"

Is The Process In Control ?

Is It Producing Defects ?





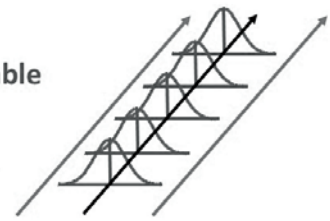
P_P & P_{PK} Measure Long-term Capability (100-200 data points)

Process/Product Variation – "Process Capability" vs "Performance"

Case 1:

Stable and Capable

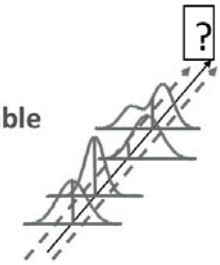
- Ideal process
- In statistical control and meets customer requirements



Case 4:

Not Stable and Not Capable

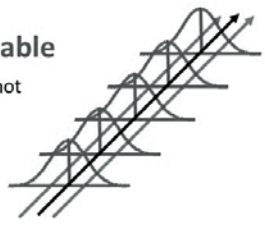
- Not in control and not acceptable
- Both special cause and common cause variation must be reduced



Case 2:

Stable but not Capable

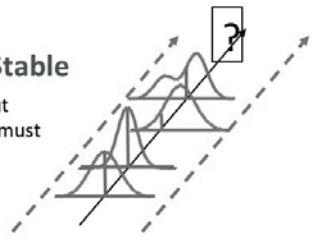
- In statistical control but not meeting Specs
- Has excessive common cause variation that must be reduced



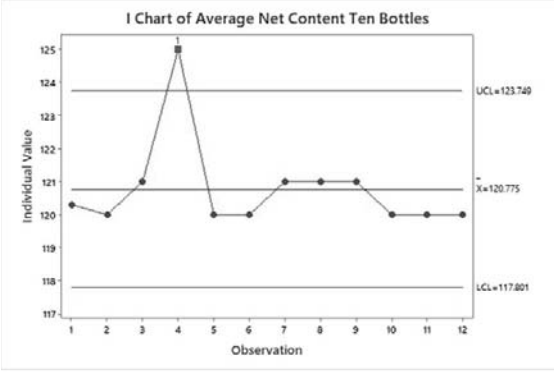
Case 3:

Capable but not Stable

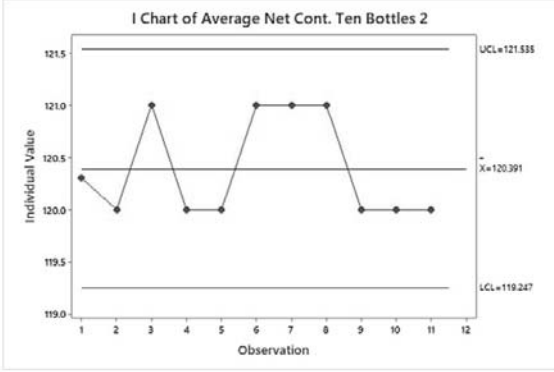
- Meets requirements but special cause variation must be reduced



Process/Product Variation – "Example of Special Cause"



Data with a Special Cause (pt. 125) **Cpk – 0.93**



Data after removing the Special Cause **Cpk – 2.09**

In the above case, removing Special Cause improves Cpk from **0.93** to **2.09**

Developing Quality and Product Robustness Metric - Quality Metrics

History of FDA's Quality metrics and quality culture initiatives

Quality Management Maturity (QMM)

The QMM program aims to encourage drug manufacturers to implement quality management practices that go beyond current good manufacturing practice (CGMP) requirements [2].

The program has four goals:

- ✓ Foster a strong quality culture mindset,
- ✓ Recognize establishments that have advanced quality management practices and acknowledge establishments that strive to continually improve quality management practices,
- ✓ Identify areas where quality management practices can be enhanced and provide suggestions for growth opportunities,
- ✓ Minimize risks to product availability to assure reliable market supply .

The QMM program is expected to help reduce the occurrence of quality-related failures and improve the ability of establishments to maintain performance during expected and unexpected supply chain disruptions

Quality Management Maturity (QMM)

QMM Ratings

- Applied to site level /not product level
- Agnostic to all manufacturing unit / Product

Regulatory Incentives

- ✓ Reduced Inspection frequency
- ✓ Flexibility in post approval changes

Market Incentives

- ✓ Consumers ready to pay more for highly rated manufacturers

QMM – Need for Digitalization

Key Inputs

- Lot Acceptance rate
- Market Complaints rate
- Valid OOS rate
- Market Recalls
- Stability Failure rate
- Invalidated OOS rate
- APQR reviews on time
- Recurring deviations
- CAPA effectiveness
- Input RM/API OOS rate
- Process capability

Challenges with manual data handling

- For Each Product & Market (Humongous data)
- Collating data in Excel at regular intervals (Manual/Electronic)
- Time consuming for reviewing of Transcription errors
- Resource intensive
- Lack of trends for decision making

Quality Metrics-Risk Based Approach

Quality Metrics – "Creating Product Quality Score Card"

Batch No	Description	Identification	LOD	UOD-AV	Drug release-Acid stage	Drug release-	Assay	RS-Ind impurity	RS-Total imp	Residual solvents
1	Complies	Complies	1.4	3.6	1	94	99.9	0.08	0.35	757
2	Complies	Complies	1.3	9.6	2	95	101.9	0.07	0.36	433
3	Complies	Complies	1.1	3.7	0	88	100.4	0.07	0.35	435
4	Complies	Complies	1.3	6.6	0	85	101.3	0.08	0.39	537
5	Complies	Complies	1.3	3	0	90	100.2	0.08	0.42	524
6	Complies	Complies	1.3	3.2	3	88	100.4	0.07	0.42	646
7	Complies	Complies	2	5.3	0	94	99.8	0.08	0.32	454
8	Complies	Complies	1.3	4.6	1	95	101.1	0.08	0.35	600
9	Complies	Complies	1.8	8.4	0	98	108	0.09	0.37	604
10	Complies	Complies	1.2	8.5	0	94	99.9	0.08	0.34	584
SD			0.7	4.64	2.99	3.96	2.59	0.01	0.07	195.15
Median			1.3	4.95	0	94	100.4	0.08	0.355	560.5
Ppk			1.72	2.17	3.35	4.79	3.71	22.27	9.92	1.51
Correction factor (CF)			0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63
Ppk*CF			1.08	1.36	2.1	3.01	2.33	13.98	6.23	1.57
Score	69	69	40.6	61.1	100	100	100	100	100	70.71
Weights	0.11	0.08	0.08	0.08	0.14	0.14	0.11	0.11	0.11	0.08
W Ppk	7.68	1.92	3.38	5.09	13.89	13.89	11.11	11.11	11.11	5.89
Product Score 85										

- Capable of being deployed for all products and compare products (Same basis of evaluation)
- Capture all key patient centric parameters
- Serve as a basis for taking preventive action – Lead indicator
- Quantified and based on statistically appropriate concepts

Use Non-parametric PpK to compute an overall Product score

Method:

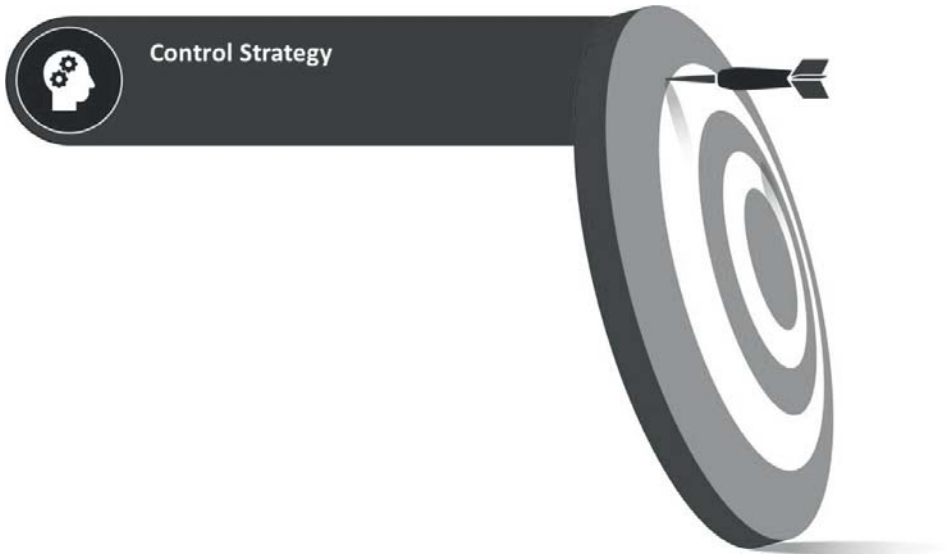
Continuous data: Non parametric calculation of PpK using medians and percentiles → Correction Factor → assign score

Discrete data: Calculate failure rate → UL of Non-conformance → assign score

- **Independent of normality assumption, batch size**
- **Sensitive to variability & closeness to specs**

Ppk Range	Score Range
Ppk <= 1	0 – 25
1 < Ppk <= 1.33	26 – 50
1.33 < Ppk <= 1.67	51 – 75
Ppk > 1.67	75 – 100

Product Robustness- How to Achieve



Flow for the Critical to Quality (CTQ) template

List of CQA's

- Provides a list of Critical Quality Attributes along with the type and criticality level for the attributes for both Finished Product and Intermediates

Impact of CPP/CMA on CQA

- Evaluates impact of CMA of API on CQAs (High/Medium/Low)
- Evaluates impact of CPP of both Intermediates and Finished Product on CQAs (High/Medium/Low)

Deep dive of impact of CMA on CQA & CS

- Provides justification for criticality of CMA for CQA

CPP & Control Strategy

- Evaluates in detail impact of CPPs and their control strategy value

List down CQAs

Level 1A : Critical Quality Attributes - Finished Product (Coated Tablet)			
S. No.	**Attribute**	**Type of attribute Safety/Quality/Efficacy**	**Criticality level of the attribute**
1	Description	Quality	Medium
2	Odor	Quality	Low
3	Identification	Quality	Medium
4	Assay (%w/w)	Efficacy	High
5	Content uniformity by UOD	Efficacy	High
6	Dissolution profile (%)	Efficacy	High
7	Related Substances limit (%w/w)	Safety	High
8	Anti-oxidant potency (%w/w)	Quality	Medium
9	Water content (%w/w)	Quality	High
10	Residual Solvents (%w/w)	Safety	Medium
11	Solid state nature of API in product	Quality	High
12	Microbial enumeration	Safety	Medium

Note: In similar lines CQA for intermediates will also be listed

Impact of CPP on CQAs

Level 2B: Evaluation of impact of CPP on CQA							
		Finished Product CQA					
S.No.	CPP \ CQA	Assay (%w/w)	Related Substances (%w/w)	Content uniformity by UOD	Dissolution profile (%)	Water content (%w/w)	Solid state nature of API in product
1	Sifting	Low	Low	Low	Low	Low	Low
2	Drug-binder solution preparation	Low	Low	Low	Low	Low	Low
3	Dry mixing	Low	Low	Low	Low	Low	Low
4	Fluid bed granulation	Low	Low	Low	High	Low	High
6	Granules drying	Low	Low	Low	Low	Low	Low
7	Milling	Low	Low	Low	Low	Low	Low
8	Blending (Pre-lubrication)	Low	Low	Low	Low	Low	Low
9	Blending (Lubrication)	Low	Low	Low	Low	Low	Low
10	Compression	Low	Low	Medium	High	Low	Low
11	Seal & Film Coating solution preparation	Low	Low	Low	Low	Low	Low
12	Seal coating	Low	Low	Low	Low	Low	Medium
13	Film coating	Low	Low	Low	Low	Low	High
14	Seal & Film coating drying	Low	Low	Low	Low	Low	Low

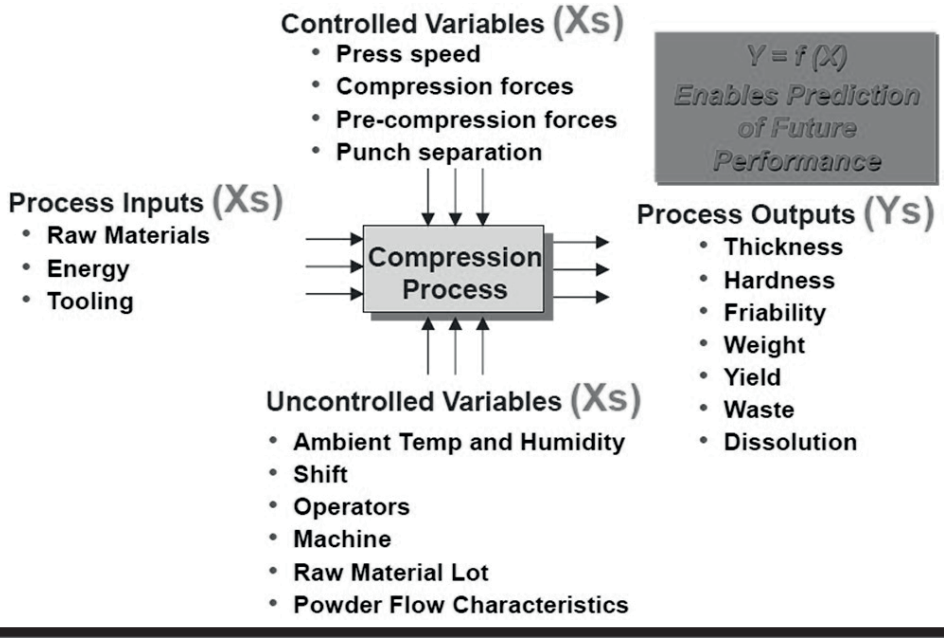
Deep dive of impact of CMA on CQA

Level 2A: Evaluation of impact of CMA on CQA									
S.No.	CMA \ CQA	Specification	Assay (%w/w)	Related Substances (%w/w)	Content uniformity by UOD	Dissolution profile (%)	Water content (%w/w)	Solid state nature of API in product	Justification for criticality (only for High/Medium)
1	Water content (API)	NMT 4.0% w/w	Low	Medium	Low	Low	Low	High	(I) API is hygroscopic in nature and is prone to hydrolytic degradtion as evident from the API forced degradation study and this may impact the related substance of the product. Hence the risk is rated as Medium. (II) Impact of water content of active on retaining the input polymorphic form of API is considered as high, because API is hygroscopic in nature and polymorphic conversion may take place due to change in the water content of API. However API water content will be controlled through API specification. Hence the risk is High.
2	Limit of Peroxides (Copovidone)	NMT 0.40% w/w	Low	Medium	Low	Low	Low	Low	The drug substance is prone to oxidation. Peroxide content may trigger oxidation of drug substance which expedite the impurity generation due to oxidation. The impurities likely have to impact on safety of product. Hence, the risk is medium.
3	Viscosity (HPMC K100 LVCR)	NLT 80 & NMT 120 mPas	Low	Low	Low	High	Low	Low	The viscosity hypromellose depends on polymer parameters like molecular weight, hydrophilicy etc. Drug release through polymer matrix is inversely proportional to viscosity of hypromellose. The viscosity of selected grade of polymer is 80-120 mPas. The lot of hypromellose used for development trials had viscosity of 98 mPas and 102 mPas. The viscosity of hypromellose towards extremity of specification (towards lower side and higher side of the specification) will have impact on drug through polymer matrix. Hence, it is rated as High.

DOE- Design Of Experiments

- Systematically chosen group of experiments where the levels of (chosen) process parameters are varied together to measure an effect on a Critical Quality Attribute (CQA)
  - Some factors are controlled while others are held constant
  - Basic Metrics
    - Number of factors
    - Number of runs
    - Confidence and power
  - Isolate effects including interactions

DOE- Predicting Process Performance



DOE- Developing Process Understanding

≡ Develop process understanding by creating "Cause and Effect" models for the process of the form:

$$Y = f(X)$$

Where:

= Y is the process output variables (CQA)

= X denotes process inputs, controlled and uncontrolled variables (CPP)

= f is a function enabling the prediction of Y given the Xs

≡ There are typically 3-6 key Xs that drive the process:

= Knowledge of these 3-6 key variables creates process understanding enabling you to optimize and control the process.

You Can't Successfully Create, Control, Improve or Transfer a Process that You Don't Understand

DOE- Comparison of Experimental Environments

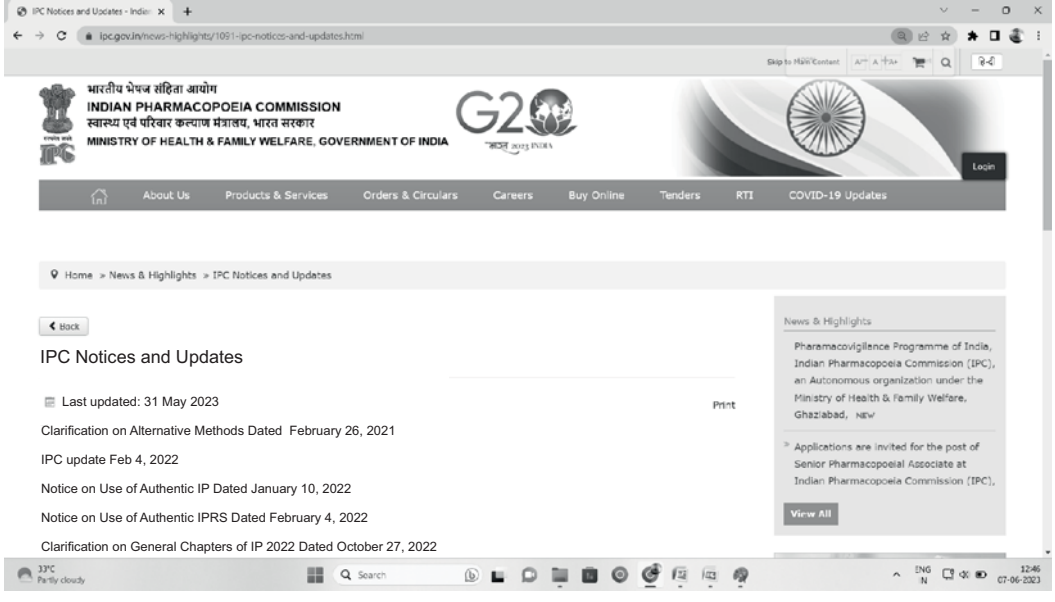
Characteristic	Screening	Characterization	Optimization
No. of Factors	>6	3-6	2-5
Desired Information	Critical Factors	Understand how system works	Prediction Equation, Optimization, **Design Space**
Model Form	Linear or Main effects	Linear & Interaction Effects	Linear, Interaction & Curvilinear Effects
Experiment Design	Plackett-Burman Fractional-Factorials DSD- Definitive screening design	Full & Fractional Factorials Taguchi Orthogonal arrays, Split Plot designs	Full & Fractional Factorials, Response Surface

CPP and Control Strategy

Level 4: Detailed evaluation of impact of critical process parameter & its Control strategy value			
Unit Operation	***Parameter***	***Value (Lab scale)***	***UOM***
Fluid bed granulation	Spray rate	36 (15-60)	g/min
	Airflow	100 (80-140)	CFM
	% inlet RH	5 -55	%
	Atomization pressure	1 (0.8-1.2)	bar
Granules drying	Inlet temperature	25-45	˚C
	EXhaust temperature	25-30	˚C
Milling	Milling speed	1200 (1200 -1700)	RPM
Blending (Lubrication)	Blending time	5	min.
Compression	Precompression force	10% of MCF	kN
	Main compression force (MCF)	20-Oct	kN
	Turret speed	20-40	RPM
Seal coating	Spray rate	2-15	g/min
	Atomization pressure	1-2	bar
Film coating	Spray rate	1-5	g/min
	Atomization pressure	2-3	bar
	Inlet temperature	30-65	˚C
	EXhaust temperature	35-45	˚C

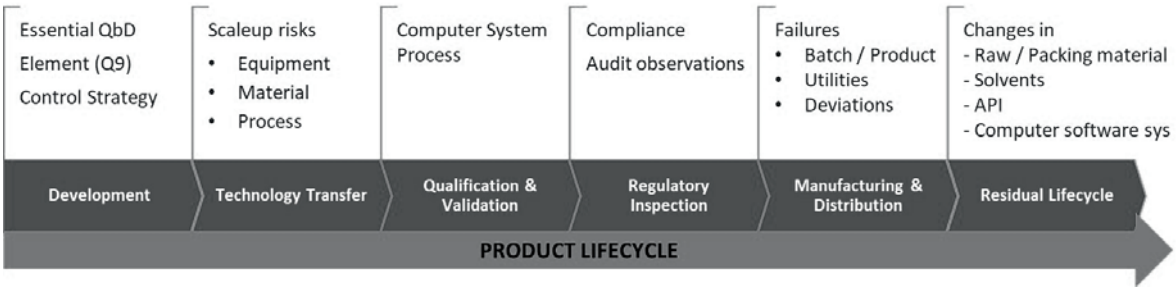
Product Robustness- How to Achieve

IPC Notices & Updates



Quality Risk Management (QRM)

"Quality Risk Management" (QRM) is performed in pharmaceutical industry to ensure that product quality is maintained throughout its lifecycle and protection of the patient is ensured by managing the risk to quality of the product and effective quality system.

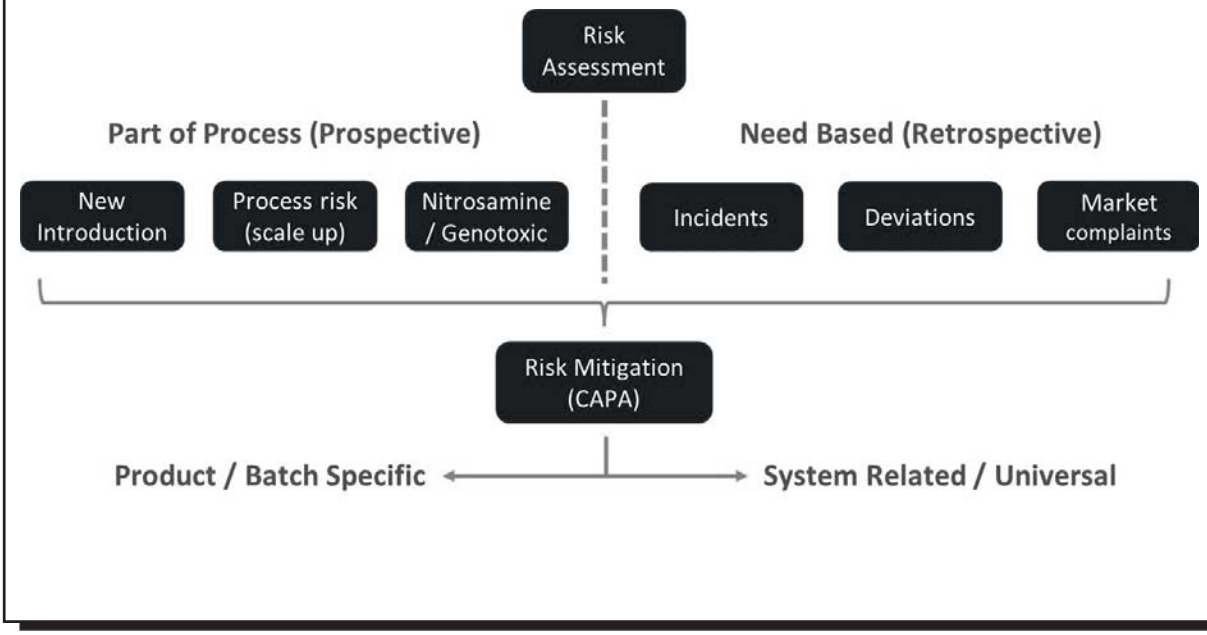


Quality Risk Management Tools

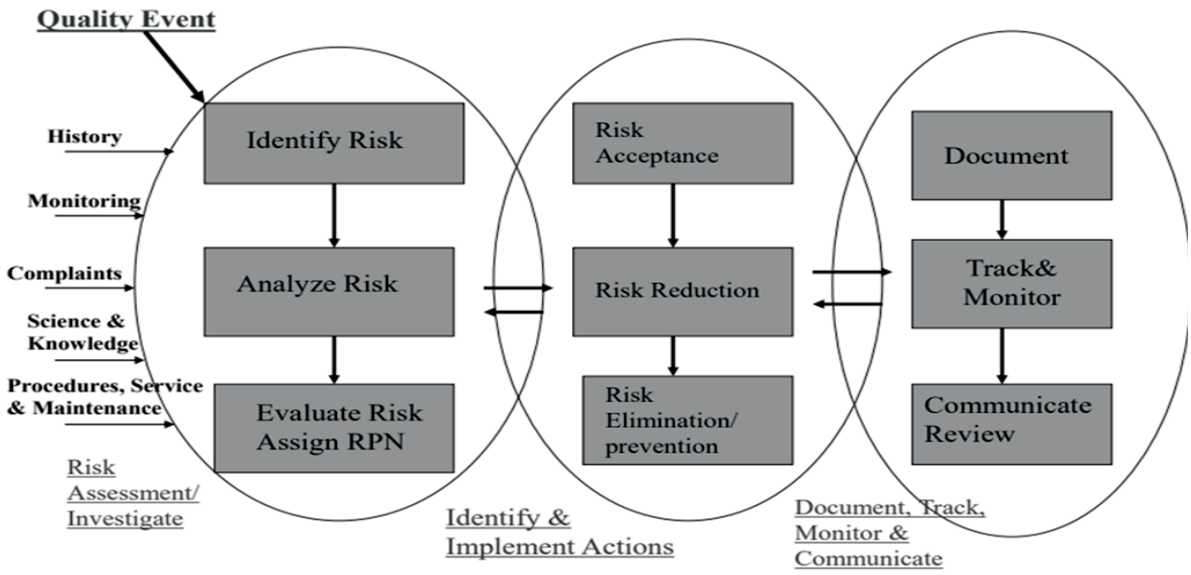
- Failure Mode and Effects Analysis (FMEA)
- Failure Mode Effects and Criticality Analysis (FMECA) and Fault Tree Analysis
- Hazard and Operability study (HAZOP)
- Hazard Analysis Critical Control Point (HACCP)
- Process Hazard Analysis (PHA)
- Ishikawa (Cause & Effect diagram)
- Risk Priority Number (RPN) Evaluation

Stage	Extent of error	S	P	Control	D	Impacted Phase	F	RPN
Blending								
Blending (Premix)	Mixing not Proper	3	1	Double Check	2	Phase impacts on qualitative & quantitative characteristics, with tested/ verified parameters.	3	18
	Documentation error	1	2	Double Check	2	No Impact on finished product.	1	4

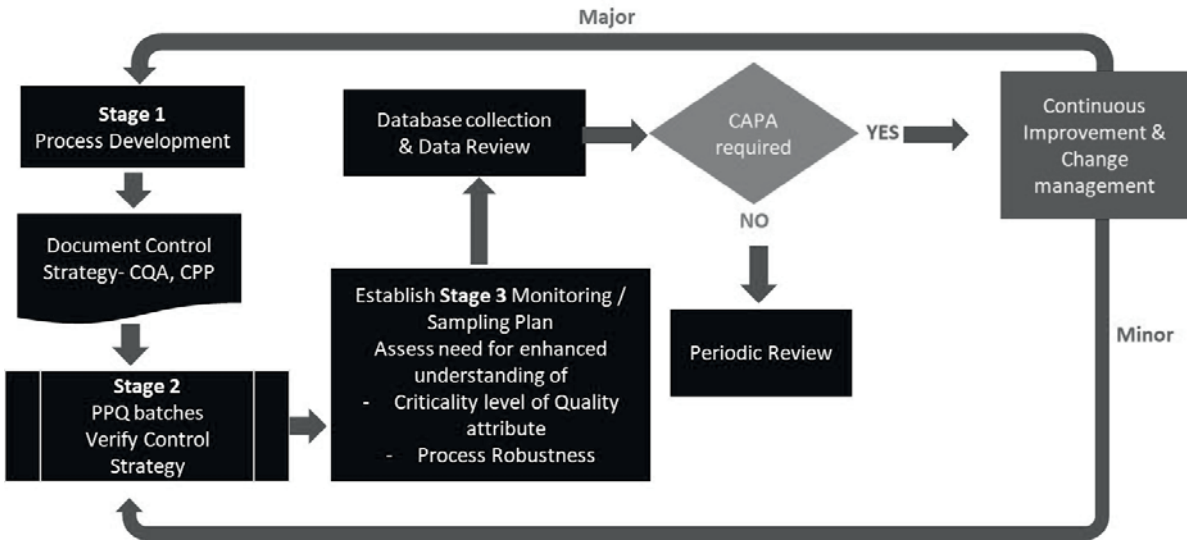
Risk Assessment – Occurrence



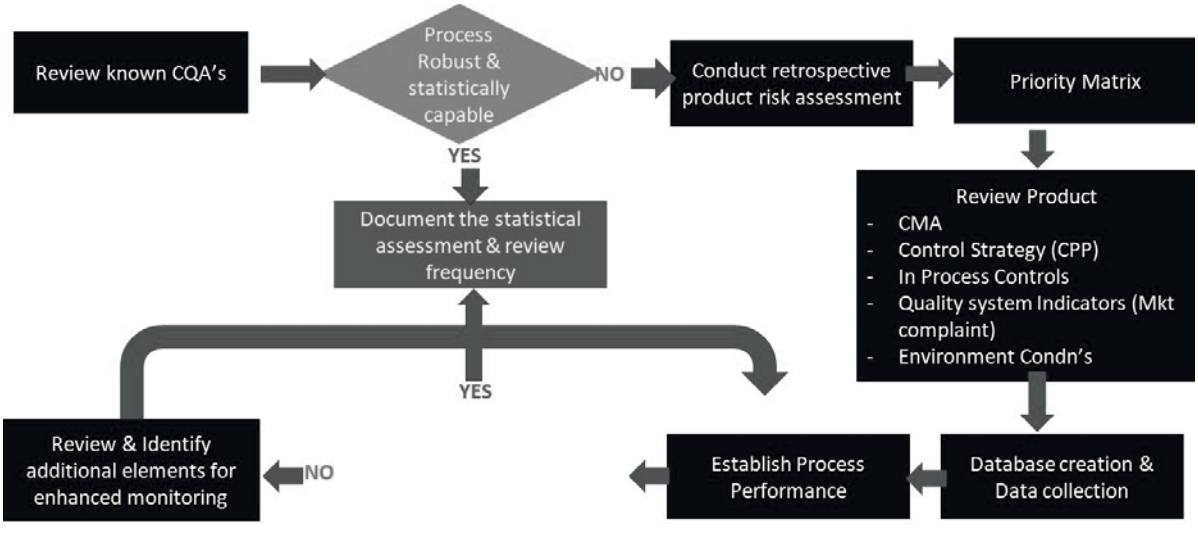
Risk Assessment – Typical CAPA approach



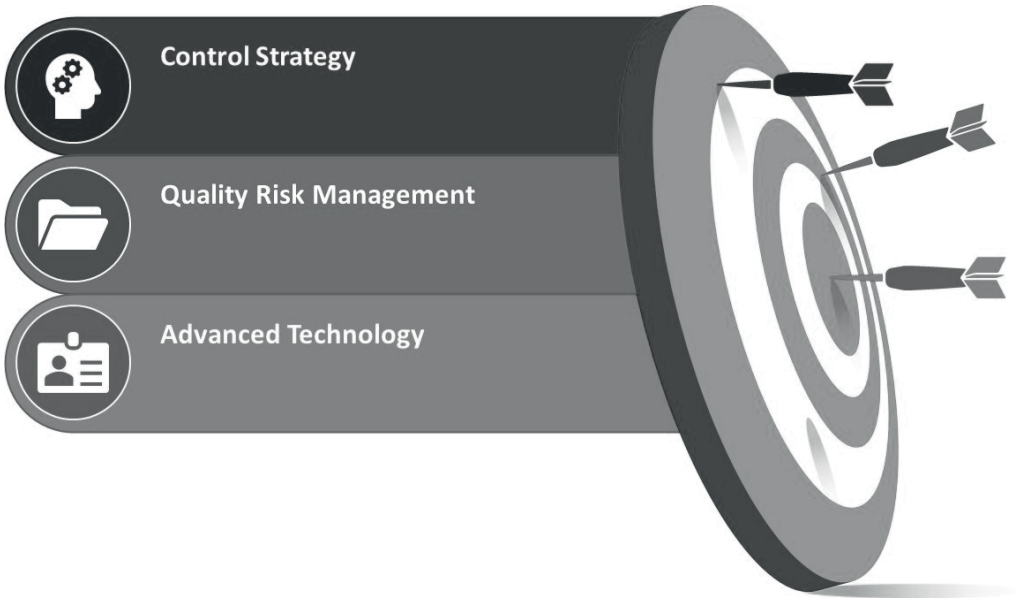
Risk-Based CPV Monitoring Plan – New Products



Risk-Based CPV Monitoring Plan – Legacy Products

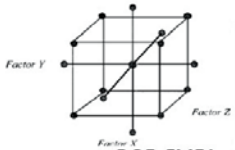


Product Robustness- How to Achieve



Application of PAT and Automation

"PAT is considered to be a system for designing, analysing and controlling manufacturing through timeline measurements (i.e., during processing of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality)"

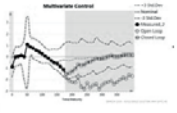


DOE, FMEA

DESIGN FOR QUALITY

SENSORS

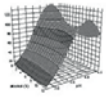
Soft- Temp, CFM
Direct- NIR, Raman



Feedback, Feedforward

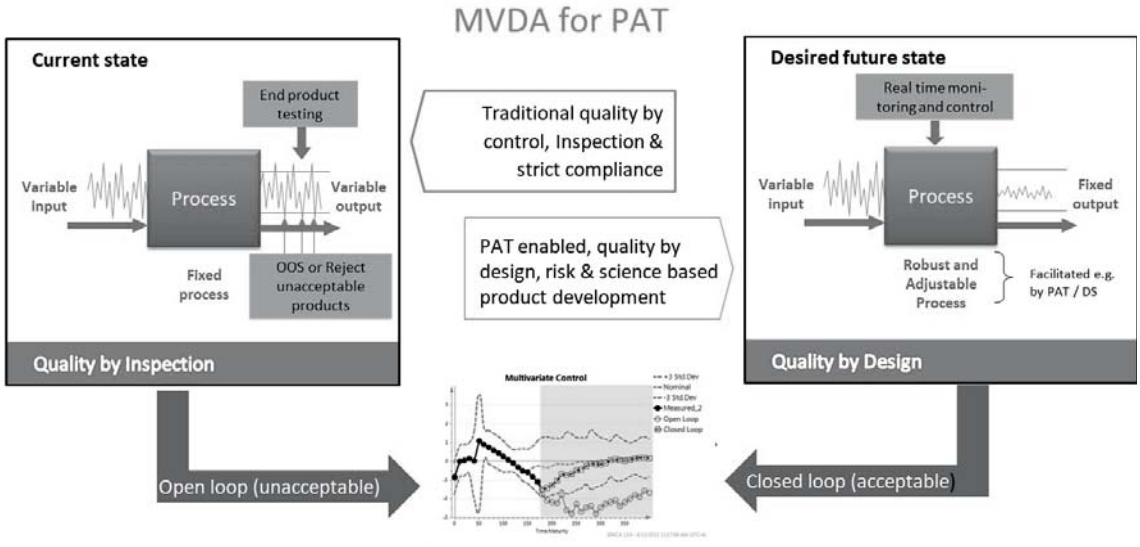
PROCESS CONTROLS

DATA ANALYSIS



Univariate, Multivariate, Real time

Application of PAT and Automation



Application of PAT and Automation

MVDA Components for online controls

- Predefined objective based on risk and scientific hypothesis specific to the application
- Relevant data
- Appropriate data analysis technique, including consideration and validation
- Appropriately trained staff
- Lifecycle management

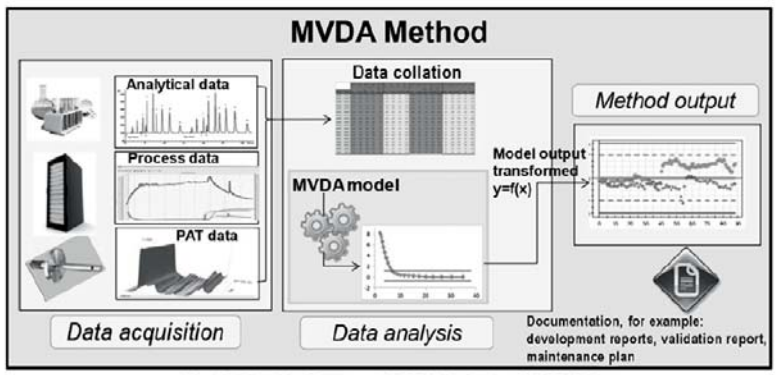
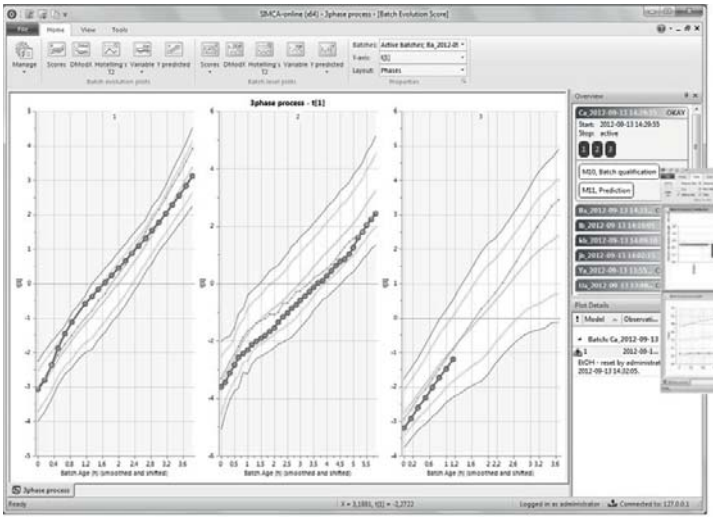


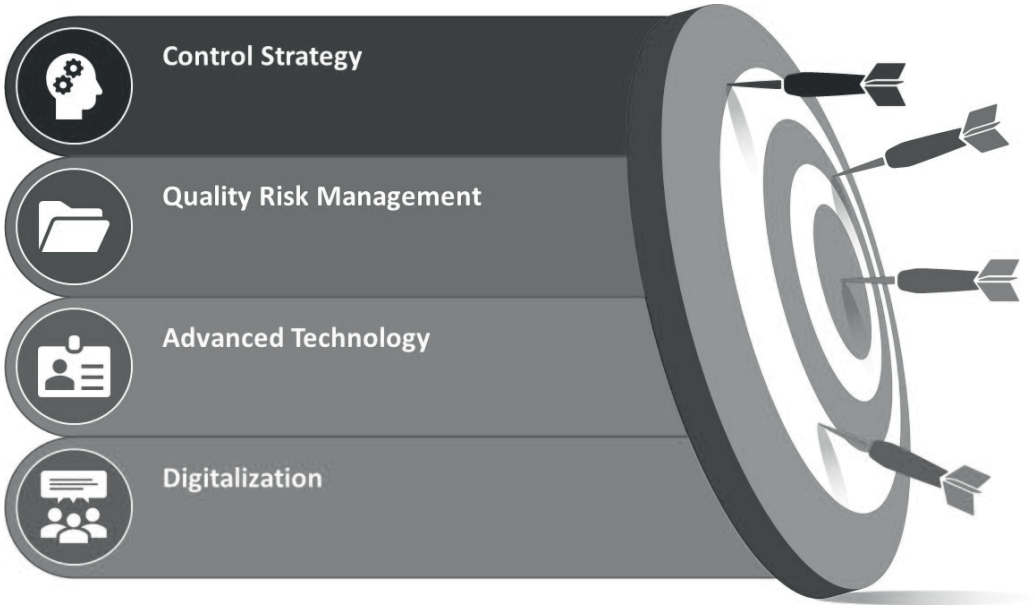
FIG. 1 Relationship Between an MVDA Method and an MVDA Model

Application of PAT and Automation

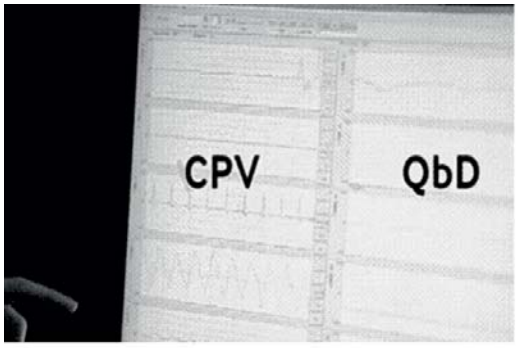


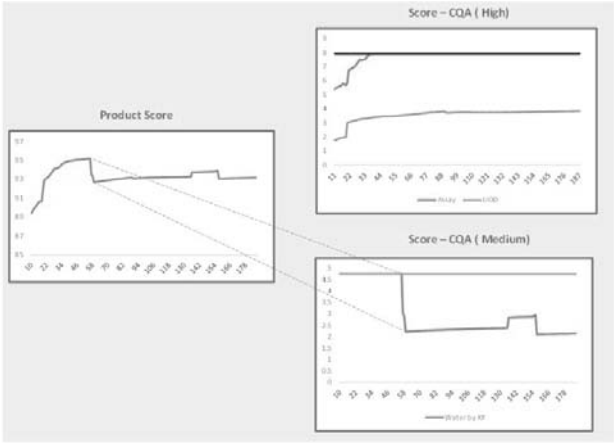
MVDA – Real-time batch monitoring

Product Robustness- How to Achieve

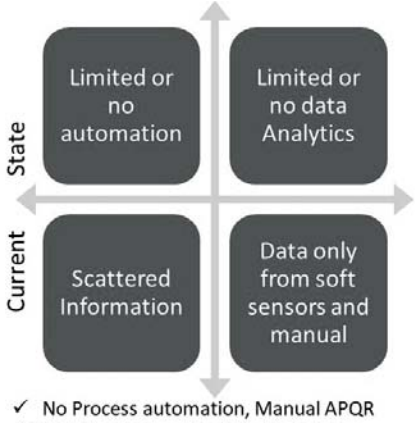


Product Scorecard – Online Tracking

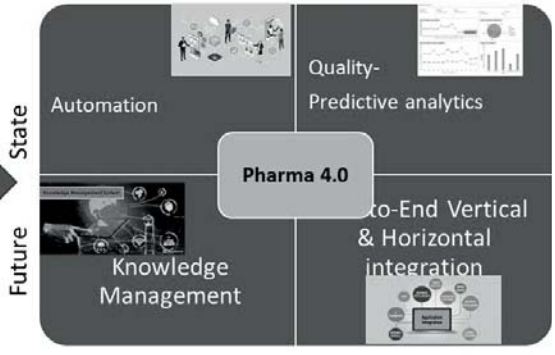




Transition to Pharma 4.0

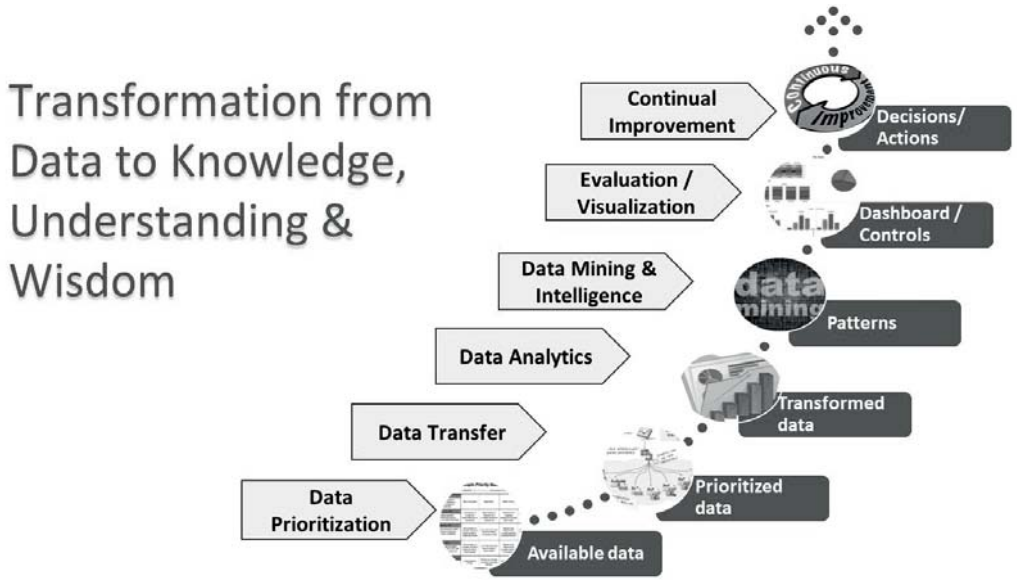


- ✓ No Process automation, Manual APQR
- ✓ End-Product testing & Batch Release
- ✓ Chance for breach of data integrity
- ✓ Preventive maintenance

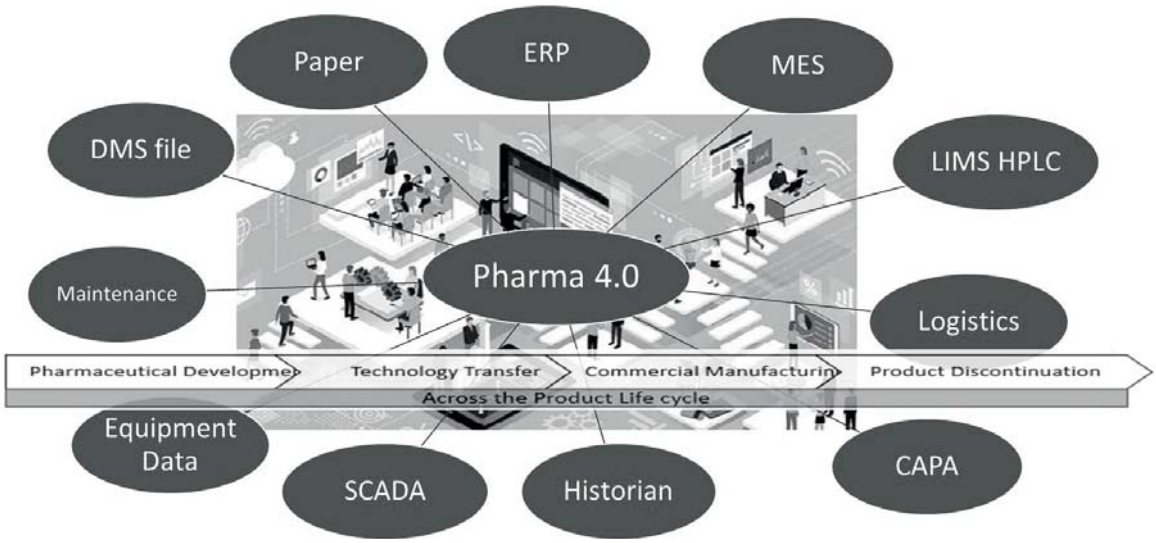


- ✓ Process automation, Continued Process verification (CPV) and Continuous Process Verification
- ✓ **R**eal **T**ime **R**elease **T**esting & Batch Release
- ✓ Enhanced data integrity
- ✓ Predictive maintenance

Pharma 4.0



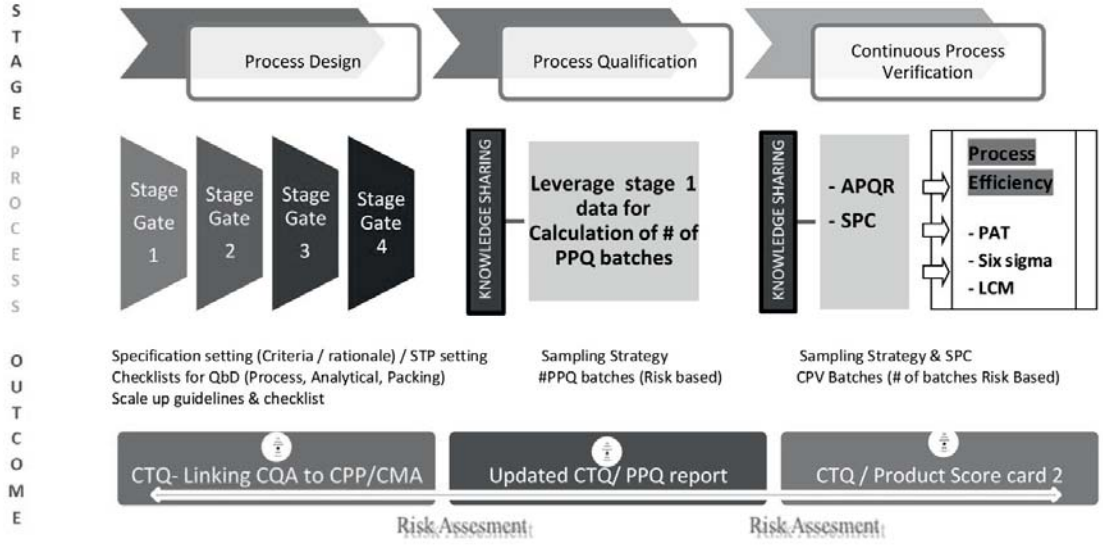
Pharma 4.0



Pharma 4.0 and Enabling the Factory of the Future

- Pharma 4.0 represents a shift away from focusing on producing to a fixed specification. Instead, Pharma 4.0 revolves around a system of real-time monitoring, simulation and control of manufacturing processes.
- The goal is to enable processes to self-adjust based on data from interconnected systems running throughout the operation. This concept builds on the principles of quality by design (QbD) and process analytical technology (PAT) that started over a decade ago in the pharmaceutical and biotech industries.

Product Robustness- Architecture



Join Pharmacists to Ensure Patient Safety

by

Mr. Hariharan. P.S
PSG College of Pharmacy, Coimbatore

Note: This article was awarded 1st prize in the Essay Competition conducted by our Trust

Introduction;

"The greatest responsibility of leader is to give the people span of care grounded sense of hope for the future"- Bob Chapman. Pharmacists play an enormous and important role in the healthcare profession. They are the backbone of providing good quality medicine to alleviate patients from pain and suffering. Pharmacists also play an important role in improving patients' quality of life. Consequently, we have made a revolution in medical history by eradicating the smallpox disease from the world. Now it's our turn. Our generation of pharmacists is joining forces with other healthcare professionals to accomplish big things.

Why we have to join?

Healthcare workers' heavy workloads can be managed more effectively through cooperation, as teamwork allows duties to be shared in a way that eases the strain on each individual. By sharing their workload, healthcare workers can reduce their stress levels and improve their overall job satisfaction. We can improve patient safety, and optimize medication use and best health outcomes by collaborating with physicians, nurses and other medical professions like biomedical, chemistry and biotechnology engineers.

Our greatest achievements by joining together;

By collaborating with other medical professionals and medical professions , Alexander Fleming discovered penicillin, which is considered the New story in the chapter of medicine and also William Procter,Jr , Dr. Charles Rice, John S. Pemberton, Jesse Boot, 1st Baron Trent ,Friedrich Sertürner, Hubert Horatio Humphrey, Jr. are the other greatest pharmacist who have collaborated with other medical professional and solved many problem which has been life threatening to patients.

Patient safety;

Over 1.3 million patients are died from tuberculosis in 2022 , and over billions of patients are infected by Tuberculosis, AIDS, Hepatitis B and other life threatening diseases.

The World Health Organization estimates that approximately 1 in 10 patients experiences harm in healthcare settings each year, tragically resulting in over 3 million fatalities annually due to deficient safety practices alone. In low-to-middle income countries, as many as 4 in 100 people die from unsafe care. Above 50% of harm (1 in every 20 patients) is preventable; half of this harm is attributed to medications. Estimates propose as many as two in five patients experience detriment within basic and outpatient environments, while nearly four-fifths of this damage has the potential to go unrealized.

Reward of joining together ;

I was thrilled to see that technologies developed by a group of pharmacists are saving countless lives in developing countries like India and Africa.

1) Manu Prakash, a biomedical engineer, collaborated with pharmacists and discovered a paper microscope that costs only 40 rupees. This microscope can detect malaria from a drop of blood and is saving countless lives in Uganda and other poor countries around the world.

2) Another example is Saad Bhalma, an Indian and brilliant pharmacist, who collaborated with a physicist and invented an 18 rupee centrifuge that spins using strings and spins ten times faster than ordinary centrifuges. The ordinary centrifuges will cost around 10,000$ which can't be afforded by poor patients.

3) I believe that these pharmaceutical and technological innovations are marvelous and are saving approximately 50 billion patients in countries with poor infrastructure.

Advancement in patient safety by pharmacist;

Thanks to the collaborative efforts between pharmacists and other healthcare professionals, recent days have seen considerable enhancements in how patient safety is ensured. Through collaboration and cooperation, we have effectively introduced diverse technological improvements, such as electronic health records, telepharmacy, medication management applications, pharmacy automation, as well as artificial intelligence.

I was truly impressed by the collaboration between pharmacists and engineers who worked together to find ways to deliver life-saving blood samples. For instance, the company Zipline partnered with pharmacists and developed Glide drones that can transport critical medical supplies to countries with numerous remote villages, such as Africa and India.

The pharamacist I know …

I know a wonderful and kind-hearted pharmacist named Jayaram who operates a pharmacy in my area. He has a great personality and is friendly with everyone. One day, he came to deliver medicine to my elderly neighbor, who was living alone without her sons who were abroad. Jayaram spoke kindly to her and explained the name of the medication, dosage, frequency, and its uses every time he visited her. He is very conscious about the health of his patients, and I realized the importance of pharmacists in our community after seeing Jayaram's dedication towards monitoring his patients' safety and health.

Benefits of joining pharmacist;

Collaborating with physicians, nurses, and other medical engineers can help us develop effective procedures and environments for patient safety. This collaboration can lead to advancements in various fields, such as the development of new generation mRNA vaccines, PSMA-targeted therapy, treatments for reducing LDL, novel drugs for diabetes, breakthrough treatments for depression, targeted medications for HCM, non-hormonal alternatives for hot flashes, new technology for menopause, vaccine-less vaccinations, and the development of new resistance-proof antibiotics against bacteria.

CONCLUSION;

In conclusion, I would like to say that pharmacists are incredible and fantastic heroes because they save billions of people's lives every year. I believe that the pharmacist's job is not limited to dispensing medicine only. They are the heroes who are important in taking care of patients, communicators who provide a good environment to patients, decision-makers in prescribing drugs to patients, managers of healthcare organizations, teachers, and life-saving scientists. "A GOOD PHYSICIAN TREAT THE PATIENT WITH DISEASE, BUT A GREAT PHARMACIST TREAT THE DISEASE".

INFORMATION

G. Rangachari Memorial (PG Pharmacy Fellowship) Awards 2023

TNPSWT, a subsidiary of IPA (Tamilnadu Branch) started in 1989 and has been doing service to profession of Pharmacy in assisting the students as well as the industry. We have a small library and also provide abstracts and text articles to under graduate and post graduate students and help IPA Tamilnadu Branch for conducting seminars, conferences etc.

Apart from above, from year 1998, we initiated Research fellowship award to selected M.Pharm and latter Pharm D (2013) final year students from various colleges in Tamilnadu, for their ongoing project work. We receive applications on synopsesfor projectfrom students, codify the synopses and sent to an evaluator outside the state of Tamilnadu for evaluation. Based on the report we make cash awards for the first, second and third ranks.

This is 26th year of this project, we have received 324 (247+77) applications from 6 different branches of M. Pharm & Pharma D

This year we have received applications from 26 institutions. All synopses were sent to **Dr. L. Sathiyanarayanan,** Vice Principal, Poona College of Pharmacy, Bharathi Vidyapeeth University, Pune – 411038 and his team. for evaluation. Based on the ranking, 21 students have been selected for Awards as per the following details:

PHARMACEUTICS

Rank	Name	College	Prize Amount (Rs.)
I	Mr. S. Amarnath	COP, Madras Medical College, Chennai	12,000
II	Mr. R. Vigneswaran	Adhiparasakthi College of Pharmacy, Melmaruvathur	10,000
III	Mr. R. Ashwin	JSS College of Pharmacy, Ooty.	8,000

PHARMACEUTICAL CHEMISTRY

Rank	Name	College	Prize Amount (Rs.)
I	Mr. M. Srinivasan	COP, Madras Medical College, Chennai	12,000
II	Mr. Krutheesh NS	JSS College of Pharmacy, Ooty.	10,000
III	Ms. G. Vinotha	Arulmigu Kalasalingam College of Pharmacy, Srivilliputhur	8,000

PHARMACEUTICAL ANALYSIS

Rank	Name	College	Prize Amount (Rs.)
I	Ms. J. Oviyaa	KMCH College of Pharmacy, Coimbatore	12,000
II	Mr. Hem Sharath. V	C.L. Baid Metha College of Pharmacy, Chennai	10,000
III	Mr. S. Ranjith	C.L. Baid Metha College of Pharmacy, Chennai	8,000

PHARMACOLOGY

Rank	Name	College	Prize Amount (Rs.)
I	Ms. Aditi Sharma	JSS College of Pharmacy, Ooty.	12,000
II	Ms. Kodali Sirisha	Swamy Vivekananda College of Pharmacy, Namakkal	10,000
III	Ms. Saranya. S	The Erode College of Pharmacy, Erode	8,000

PHARMACOGNOSY

Rank	Name	College	Prize Amount
I	Ms. Monisha. T	COP, Madras Medical College, Chennai	12,000
II	Ms. Keerthana. T	COP, Madurai Medical College, Madurai	10,000
III	Ms. M. Kaviyarasi	COP, Madras Medical College, Chennai	8,000

PHARMACY PRACTICE

Rank	Name	College	Prize Amount (Rs.)
I	Mr. Divakar. G	PSG College of Pharmacy, Coimbatore	12,000
II	Ms. Challa Kusuma Chowdari	SRM College of Pharmacy, Chennai	10,000
III	Mr. Akash Ganga. R	SRM College of Pharmacy, Chennai	8,000

PHARM D

Rank	Name	College	Prize Amount (Rs.)
I	Ms. Nethra R, Ms. Poojaa Shri N, Ms. Pricilla V.	College of Pharmacy, SRIPMS, Coimbatore	15,000
II	Mr. Jothiswaran R, Ms. Keerthana S, Mr. Muthu Prasath M.K.	College of Pharmacy, SRIPMS, Coimbatore	12,000
III	Mr. Sethuraman K, Ms. Shalini S, Ms. Sharon Ishwarya Roy	College of Pharmacy, SRIPMS, Coimbatore	10,000

Shri. G. Swaminthan Memorial Award - Essay Competition 2023 –

Final Year B. Pharm Students

TNPSWT imitated a new activity from 2011 for Essay competition and this year subject being "**Join Pharmacists to ensure Patient Safety**". This awarded is in the name of "**Shri. G. Swaminthan Memorial Award**" -- Sponsored by M/s. Pharm Product Pvt Ltd. Thanjavur.

This year we have received 77 applications from 19 colleges and this was evaluated by **Mrs. Anusuya R Kashi**, Asst. Professor, Vivekananda College of Pharmacy, Bangalore – 560055.

Based on the rating -- 3 students have been awarded as below

Rank	Name of the Student	College	Amount
I	Mr. Hariharan. P.S	PSG College of Pharmacy, Coimbatore	10,000
II	Mr. Sathiya Raj. R	COP, SRIPMS, Coimbatore	8,000
III	Ms. Saranya Devi. C.S.	PSG College of Pharmacy, Coimbatore	7,000

We thank Mr. T. Ravichandran M/s. Pharma Products Pvt Ltd, Thanjavur for the above awards

Fourrts University Merit Award 2023

From year 2015 M/s. Fourrts India ltd sponsored university merit award for topper candidates, who have secured high marks in B.Pharm examinations passed during September 2022, examinations held in March 2023 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Rank	Name of the Student	College	Prize Amount (Rs.)
I	Ms. Vinothini. S	Senghundhar College of Pharmacy, Namakkal	10,000
II	Ms.BhuvanaPriya S. L	C. L. Baid Metha College of Pharmacy, Chennai	8,000
III	Ms. Afreen. V	K. K. College of Pharmacy, Chennai	7,000

We thank to **Mr. S. V. Veerramnai,** Chairman & Managing Director, **M/s. Fourrts (India)LaboratoriesPvt Ltd, Chennai,** for the above awards

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th November, 2023

S.O. 4834(E).—In exercise of the powers conferred by sub-section(2) of section 1of the Jan Vishwas (Amendment of Provisions) Act, 2023 (18 of 2023), the Central Government hereby appoint the date of publication as the day on which the provision at serial no. 35 in the Schedule of the Jan Vishwas (Amendment of Provisions) Act, 2023 relating to Food safety and Standards Act, 2006 (34 of 2006) shall come into force.

[F. No. P.15025/113/2022-FR]

ARADHANA PATNAIK, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 28th December, 2023

G.S.R. 922(E).—Whereas, a draft of certain rules further to amend the Drugs Rules, 1945 was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) (thereafter referred to as the said Act) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 999(E), dated the 5th October, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days **from the date on** which the copies of the said Official Gazette containing the said notification were made available to the public;

And, whereas, copies of the said Gazette were made available to the public on 9th October, 2018;

And, whereas, objections or suggestions received from the public on the said rules were considered by the Central Government;

For further details please visit the link
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTU=

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 2nd February, 2024

G.S.R. 91(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby appoints the persons specified in column (2) of the Table given below as Government Analysts at the National Institute of Biologicals, Plot No. A-32, Sector 62, Institutional Area, Noida, Uttar Pradesh – 201309, for the whole of India in respect of the classes of drugs specified against their names in column (3) of said Table, namely:—

TABLE

Sl. No.	Name and Designation of the Government Analyst	Classes of Drugs
(1)	(2)	(3)
1.	Dr. Ratnesh Kumar Sharma Scientist Grade-II,	Therapeutic Monoclonal Antibody Products - (i) Nivolumab; (ii) Denosumab; and 2. (iii) Ranibizumab
2.	Dr. Saurabh Sharma Scientist Grade-III,	
3.	Dr. Manoj Kumar, Scientist Grade-III,	(i) Human Albumin; (ii) Human Normal Immunoglobulin (Intramuscular and Intravenous) ; (iii) Human Coagulation Factor VIII; (iv) Human Coagulation Factor IX; (v) Plasma Protein Fraction; (vi) Fibrin Sealant Kit; (vii) Anti-Inhibitor Coagulant Complex; and (viii) *Rabies Immunoglobulin.
4.	Sh. Tara Chand Scientist Grade-III,	

* Potency assay of Rabies Immunoglobulin is performed by USP 43.

[F. No. X.11035/79/2019-DR]
RAJIV WADHAWAN, Advisor (Cost)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi the 5th February, 2024

G.S.R. 95(E).— Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Ministry of Health and Family Welfare, Government of India, number G.S.R. 686 (E) dated 25th September, 2023 published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i), inviting objections and suggestions from the persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And, whereas, copies of the Gazette were made available to the public on 25.09.2023;

And, whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:

1. (1) These rules may be called the Drugs (Amendment) Rules, 2024.

   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs Rules, 1945, in Schedule H1, after serial number 48 and entries relating thereto, the following serial number and entry shall be inserted, namely:-

   "49. Oseltamivir

   50. Zanamivir".

[F. No. X.11014/10/2016-DRS]
RAJIV WADHAWAN, Advisor (Cost).

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 922(E), dated the 28th December, 2023.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th February, 2024

S.O. 476(E).— In exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby rescinds the notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide G.S.R. 144(E), dated the 17th February, 2017, with immediate effect except as respects things done or omitted to be done before such rescission.

[F. No. X.11014/10/2016-DRS]
RAJIV WADHAWAN, Advisor (Cost)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 6th February, 2024

S.O. 567(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby appoints —

i. Shri. Arijit Saha, Research Assistant (Biochemistry);

ii. Shri. Turjya Ray, Research Assistant (Pharmaceutical Chemistry), at the Central Drugs Testing Laboratory, Indore to be the Government Analysts for the whole of India in respect of all classes of drugs except the classes of drugs mentioned below, namely:—

1. Sera ;
2. Solution of Serum Proteins intended for injection ;
3. Vaccines ;
4. Toxins ;
5. Antigens ;
6. Anti-toxins ;
7. Sterilised surgical ligature and sterilised suture ;
8. Bacteriophages ;
9. Anti-Sera for Veterinary use ;
10. Vaccines for Veterinary use ;
11. Toxoids for Veterinary use ;
12. Diagnostic Antigens for Veterinary use ;
13. Venereal Disease Research Laboratory Antigen ;
14. Human Blood and Human Blood Products including components, to test for freedom for Human Immunodeficiency Virus antibodies;
15. Blood Grouping reagents and diagnostics kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis E Virus; and
16. Condoms.

[F. No. X.11035/144/2023-DRS]
RAJIV WADHAWAN, Adviser (Cost)

F. No. 12-107/2023-DC(Pt-MISC-SND)
Central Drugs Standard Control Organisation
Ministry of Health and Family Welfare
Govt. of India
(SND DIVISION)

Date: 5th December, 2023

ADVISORY

Under the Drugs and Cosmetics Act and Rules there under the drug manufacturers are required to manufacture the drugs adhering strictly to the conditions of manufacturing license and prescribed Good Manufacturing Practices to ensure that the drugs manufactured for marketing are of quality standards and meets the parameters of quality, safety and efficacy.

In order to ensure quality, safety and efficacy of drugs formulation it is of paramount importance that such formulation are manufactured in compliance with the prescribed standards not only in respect of API but also various excipients used for manufacturing of the formulations. Therefore, the quality, safety and efficacy of both APIs and the excipients are crucial.

In case of manufacture of cough syrups, various critical excipients like propylene glycol, glycerine, sorbitol etc. are used. The manufacturers are required to ensure that these excipients meet the regulatory standards of quality so as to avoid any contamination in the formulations manufactured by using such excipients During winter seasons, there may be increase in use of cough syrups in the country.

In view of above, the manufacturers are hereby advised that they should purchase and use only pharma grade excipients from their approved sources/vendors which are of quality standards in accordance with the regulatory requirements under the provisions of the said Act & Rules to ensure quality, safety and efficacy of the drug formulations.

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

To
All Stakeholders & CDSCO Website

Copy to:

1) All State / UT Drugs Controllers to direct all the manufacturers under their jurisdiction to use only pharma grade excipients in manufacturing of drug formulations
2) All Zonal & Sub Zonal offices of CDSCO for follow up with the concerned State

Copy for information to:

1) PPS to AS (Regulation), MoHF&W, Nirman Bhawan, New Delhi

File No.: 04-01/2022-DC (Misc.-47)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

To,
All State/UTs Drugs Controllers,

18 DEC 2023

Subject: To update package insert/Promotional Literature of FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml - regarding.

Sir,

The FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml was declared as rational by Prof. Kokate committee and based on the recommendation of the committee, this office has issued NOC for continued manufacturing and marketing of subject FDC on 17.07.2015 under the 18 months policy decision.

Subsequently concerns have been raised regarding promotion of unapproved anti-cold drug formulation for infants. The matter was deliberated in Subject Expert Committee (SEC- Pulmonary) meeting held on 06.06.2023 wherein, In light of the issue regarding use of the FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCL IP 5mg drop/ml was discussed before the committee. The committee recommended that the FDC should not be used in children below 4 years of age and accordingly the firms should mention warning in this regard on label and package insert.

The recommendation of the SEC has been considered by this office.

Accordingly, you are requested to direct all the manufacturers of said FDC under your jurisdiction to mention warning "**FDC should not be used in children below 4 years of age**" on label and package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:-
1. All Zonal/Sub Zonal offices of CDSCO
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

Notice

File No.: IT-13011(11)/1/2023-eoffice **Date:** 16 JAN 2024

Subject – Launching of additional Forms on National Single Window System (NSWS) Portal- reg.

This is in continuation to this office notice dated 01.01.2024 whereby 3 Forms i.e. MD-01, MD-12 and MD-16 were made 'Live' on NSWS portal w.e.f. 01.01.2024.

Now following additional Forms have also been developed and will be made 'Live' on NSWS w.e.f. **16.01.2024**:-

1. Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis- CT-10.
2. Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study-CT-12.
3. Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study-CT-13.
4. Application for grant of licence to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis -CT-16.

Further Form 12 i.e. 'Application for licence to import drugs for purpose of examination, test or analysis' will also be made 'Live' on **24.01.2024**.

In view of above, it is requested that all concerned stakeholders henceforth should submit application related to above said five activities through NSWS portal only and the existing SUGAM online portal for the said activities will be disabled w.e.f. **10.02.2024.**

The NSWS portal can be browsed through *https://www.nsws.gov.in* and a user guide is also attached herewith for guidance for ready reference.

This is for information of all concerned stakeholders.

Encl.: As above

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:

1. All the concerned stakeholders
2. CDSCO Website

NEWS

No More Painful Insulin Shots: Hyderabad Company Develops Oral Insulin Spray for Diabetes

Hyderabad-based NiedlFree Technologies, a company affiliated with Transgene Biotek, has made significant progress in the field of diabetes treatment. They claim to have developed a painless and needle-free oral insulin spray called Ozulin, which can be used by both animals and humans. This breakthrough could potentially make controlling blood sugar levels as simple as spraying insulin into the mouth, a TOI report stated.

NiedlFree Technologies has applied to the Central Drugs Standard Control Organisation (CDSCO) for permission to conduct safety and toxicology studies before proceeding with human clinical trials. Dr. K Koteswara Rao, the co-founder and director of NiedlFree Technologies and CMD of Transgene Biotek, revealed that the company has obtained global patents for Ozulin in over 40 countries.

In addition to diabetes treatment, NiedlFree Technologies is also working on developing oral and nasal sprays for cancer, osteoporosis, and Alzheimer's. To bring these drugs to the market, the company plans to raise $225-250 million in funding over the next few years.

Dr. Rao emphasized the potential impact of Ozulin on diabetes care, stating that the global market for Type 1 and Type 2 diabetes treatment is estimated to be around $78 billion by 2022. In a recent study conducted by Palamur Biosciences on dogs, Ozulin demonstrated a bioavailability of over 91% compared to injectable insulin. This promising result indicates the effectiveness of the oral insulin spray.

Dr. Rao explained that NiedlFree Technologies achieved this breakthrough by encapsulating human insulin into functionalized nano particles, ensuring optimal delivery into the bloodstream with a prolonged release. Many biopharma companies worldwide have attempted to develop oral insulin, but with limited success in achieving sufficient insulin absorption into the bloodstream.

The company plans to introduce the oral insulin spray for pets, primarily dogs and cats, by 2024-25. This development signifies a significant advancement in diabetes treatment, offering a painless and needle-free alternative for insulin administration.

Source: *The Economics Time,* 2nd November 2023

Health Ministry Releases Draft National Pharmacy Commission Bill

The Union Health Ministry has released the draft National Pharmacy Commission Bill, 2023, which seeks to repeal the Pharmacy Act of 1948 and replace the Pharmacy Council of India with a national commission.

The ministry put up the draft bill on its website on November 14 seeking comments from the public.

The proposed bill aims to provide for a pharmacy education system that improves access to quality and affordable pharmacy or pharmaceutical education, ensures availability of adequate and high-quality pharmacy professionals in all parts of the country, promotes equitable and universal healthcare, and makes services of pharmacy professionals accessible to all citizens.

The draft bill calls for a periodic and transparent assessment of pharmacy institutions, facilitating maintenance of a pharmacy register for India, and enforcing high ethical standards in all aspects of pharmacy services.

It also encourages pharmacy professionals to adopt latest pharmacy research in their work and to contribute to research.

The draft bill proposes flexibility to adapt to changing needs and seeks to set up an effective grievance redressal mechanism. According to the draft, the Pharmacy Ethics and Registration Board will maintain a National Pharmacy Register which will have details of pharmacy professionals to ensure transparency.

Source: *The Indian Express,* 20th November 2023

Government Fixes Price Ceiling for 9 Drug Formulations

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price of nine drug formulations. This includes Tacrolimus – an immunosuppressive drug used to reduce the risk of rejection of organ post-transplant and Co-trimoxazole that is used to treat bacterial infections that cause pneumonia and urinary tract infection among others.

The pricing authority has set the retail prices for the drug Tacrolimus (0.5 mg) at Rs 20.97. The price of Tacrolimus 1 mg and 2 mg has been fixed at Rs 39.98 and Rs 77.69 respectively.

In case the retail price of any of the above formulations is not complied with, as per instant price notification, then the concerned manufacturer or marketing company shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the DPCO 2013, read with the Essential Commodities Act, 1955.

According to the latest NPPA order, the ceiling price of Co-trimoxazole has been fixed at Rs 2.30 and the price of zinc sulphate tablets (20 mg) has been fixed at Rs 3.41.

The NPPA has also revised the ceiling price of painkiller drug Tramadol (50 mg) at Rs 9.70. The price of anti-cancer drug Temozolomide (20 mg) has been fixed at the rate of Rs 336.63.

"All the existing manufacturers of above-mentioned scheduled formulations having minimum retail price (MRP) lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO (Drug Price Control Orders), 2013," the NPPA order states.

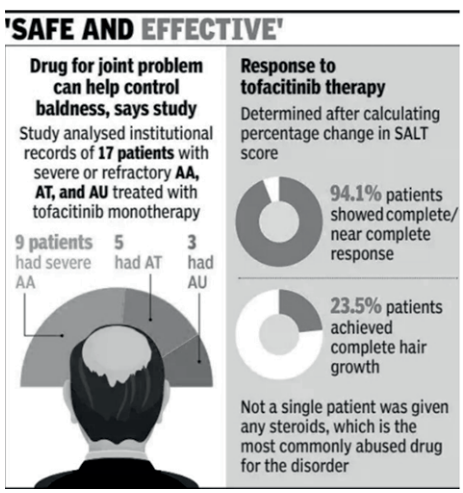
Recently, the NPPA also extended the ceiling price fixation for orthopaedic knee implants for one more year till September 15, 2024.

Officials have said that this has been made to ensure that the implants are affordable and accesible, also to stop fleecing of patients.

Source: *The Times of India,* 21st November 2023

From Joints to Locks: Drug Used for Arthritis can Help Control Baldness, Says Recent Study

Tofacitinib, a drug commonly used to treat rheumatoid arthritis and ankylosing spondylitis, has shown excellent results in treatment of an autoimmune disorder, alopecia areata (AA) — sudden hair loss that starts with one or more circular bald patches, reveals a study.



Published last week in an online journal, Indian Dermatology, the study stated that 94.1% of the alopecia areata patients covered showed complete/near complete response with this medicine. At least 23.5% achieved complete hair growth on tofacitinib monotherapy in eight months and maintained it on 5mg alternate day without any relapse. The mean age of patients was 17.6 years, and ranged from 5 to 34 years, with a male-to-female ratio of 8:1.

The lead author of the study, Dr Kabir Sardana of the dermatology department of RML Hospital, said tofacitinib was found to be safe and effective in severe cases of alopecia areata along with alopecia universalis (AU), complete hair loss on your scalp and body,and for alopecia totalis (AT), complete hair loss on

the scalp, patients recalcitrant to other treatment modalities. However, the drug has shown poor results in patients suffering for more than 10 years or if it has appeared in the first threeyears of their life.

"It's a remarkably safe drug. Side effects have been seen only in elderly people and those with heart issues," he said, adding that auto immune disorders tend to recur so one needs to take it as and when needed. The other option was oral steroids, which have many more side effects and are widely abused.

The primary aim of the study was to assess the complete response rates to tofacitinib monotherapy in severe and recalcitrant AA, AT and AU patients using the latest percentage change in severity of alopecia tool (SALT) score, commonly used for quantifying the amount of scalp hair loss in clinical trials. "The secondary aim was to analyse various systemic agents used by these patients prior to the use of tofacitinib," said authors.

They said the institutional records of 17 patients with severe or refractory AA, AT, and AU treated with tofacitinib monotherapy were analysed, retrospectively. The response to the therapy was determined after calculating the percentage change in SALT scores.

According to the study, nine of the 17 patients had severe AA, while five patients had AT and three had AU. All patients had earlier received either systemic glucocorticoids, which included oral mini pulse, intravenous pulse steroids and daily oral GCS or immunosuppressive agents. The mean SALT score prior to starting tofacitinib was 74.23.

The mean dose of tofacitinib was 13.23mg (10-15mg) for the mean duration of 9.2 months. The latest percentage change of SALT score ranged from 70.6% to 100%, with an average of 91.5%. The study stated that furtherresearch was needed to assess the long-term efficacy of tofacitinib.

Source: *The Times of India,* 21st November 2023

Drug Licences of Chemists Suspended

The state directorate of drug control has cancelled licences of six chemists who sold habit-forming drugs, including painkillers, to people without prescriptions over the last six months, health secretary Gagandeep Singh Bedi said. At least 117 licences were suspended temporarily for violations under the Drugs and Cosmetics Act, 1940, he said.

The state health department had recently received reports from the police about the sale of habit-forming drugs across the state without prescriptions from doctors. "We have formed teams to crack down on such sales. Drug inspectors will inspect pharmacies in their region at least three times a week to check on sales records. They will be accompanied by police," Bedi said.

Source: *The Times of India,* 23rd November 2023

Generic Drugs to Treat Four Rare Diseases Launched

Providing relief to patients with rare diseases across India, the Union Health Ministry has made available generic drugs to support the care and treatment of four ailments: Tyrosinemia-Type 1, Gauchers Disease, Wilson's Disease, and the Dravet-Lennox Gastaut Syndrome. This means that the cost of these drugs will be slashed by anywhere between 60 and 100 times of their current market value.

The Ministry is also in the process of making available drugs for more rare diseases, including Phenylketonuria and Hyperammonemia, over the next few months. “The approvals for these drugs are awaited,” said V.K. Paul, NITI Aayog's member with expertise on health issues. He added that this initiative would also result in patients' costs dropping from crores annually to mere lakhs. Additionally, a sickle cell disease drug formulation will now be made available for children.

A rare disease is a health condition of particularly low prevalence that affects a small number of people. It collectively afflicts 6-8% of the population in any country at any given time, so India could have 8.4 crore to 10 crore such cases, according to the Ministry. Nearly 80% percent of these diseases are genetic in nature.

Priority diseases

“To bring in these drugs a special initiative was taken, and discussions were held with academia, pharma industries, organisations, the Drug Controller, and the Department of Pharmaceuticals. Thirteen rare diseases were prioritised. We particularly worked on sickle cell disease, and on the syrup for children under five who can't be administered tablets,” said Health Minister Mansukh Mandaviya.

“This venture is purely a non-commercial venture guided only with the motive to serve those in acute need. For years, the Health Ministry through various schemes has been trying to financially help as many patients as possible but this is a more sustainable measure for not just patients in India but also worldwide,” he said.

Dr. Paul added that the Ministry was also engaging with companies who are selling patented rare disease drugs. “We are actively looking at how best to work for patients who urgently need these medicines,” he explained.

Several companies -- including Biophore India, Laurus Labs, Azico Biophore, MSN Pharmaceuticals, Akums Drugs and Pharmaceutical – have come forward to take part in the venture.

Source: *The Hindu,* 24th November 2023

Popular Painkillers with Mefenamic Acid Could Cause DRESS Syndrome: Govt Advisory

Popping painkillers with Mefenamic acid could have adverse side effects, including drug reactions, rashes, hypersensitivity, and death in some cases.

Mefenamic acid, a common painkiller, is used to relieve menstrual pains, headaches, and muscle and joint pain, and also for children in cases of high fever. It is also used to treat rheumatoid arthritis, osteoarthritis, and dysmenorrhea.

The Pharma standard body, in its preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database, revealed that Mefenamic acid can lead to Drug Reactions with Eosinophilia and Systemic Symptoms (DRESS) syndrome.

Typically, DRESS syndrome is an adverse reaction term that describes a hypersensitivity reaction with an estimated mortality of up to 10 per cent.

In a monthly drug safety alert notice issued by the Pharma standard body Indian Pharmacopoeia Commission (IPC), doctors and patients have been advised against the use of this painkiller, and to report immediately if adverse side effects are noticed.

The drug is sold under various brand names that include Meftal, Mefkind P, Ponstan, Mefanorm, and Ibuclin P, among others. These cannot be sold without prescriptions.

The Pharmacovigilance Program of India (PvPI) monitors and collects information about adverse drug reactions (ADRs) and adverse events associated with pharmaceutical products.

"Healthcare professionals, patients, consumers are advised to closely monitor the possibility associated with the use of suspected drug," the advisory reads.

Source: *The Hindu Businessline,* 7th December 2023

DCGI Asks Pharma Cos to Adhere to Production Quality Standards

The Drugs Controller General of India (DCGI) has issued an advisory stating that pharmaceutical companies are required to strictly abide by conditions stated in their manufacturing licences and prescribed Good Manufacturing Practices (GMP) to ensure that the products meet parameters of quality, safety and efficacy.

The DCGI's move comes a few days after ET reported that industrial excipients are used in manufacturing medicines and over 50 companies manufacturing cough syrups have failed quality tests. The World Health Organization (WHO) said in October last year that the deaths of dozens of children in Gambia from acute kidney injuries might be linked to contaminated cough and cold syrups made by an Indian drug manufacturer.

"In order to ensure quality, safety and efficacy of drug formulation, it is of paramount importance that such formulations are manufactured in compliance with the prescribed standards not only in respect of API (active pharmaceutical ingredient) but also various excipients used for manufacturing of the formulations. Therefore, the quality, safety and efficacy of both APIs and the excipients are crucial," according to the advisory.

In the case of cough syrups, as various critical excipients like propylene glycol, glycerine, sorbitol, etc. are used, the drug regulator said companies are required to ensure that the excipients meet the regulatory norms on quality to avoid contamination in the formulations produced from such excipients.

"In view of above, the manufacturers are hereby advised that they should purchase and use only Pharma grade excipients from their approved sources/vendors which are of quality standards in accordance with the regulatory requirements under the provisions of the said Act & Rules to ensure quality, safety and efficacy of the drug formulations," the advisory said.

The DCGI's advisory gains significance as the on going winter season tends to see increased use of cough syrups in the country.

In a separate note, DCGI Rajeev Singh Raghuvanshi referred to quality concerns reported for propylene glycol (PG) supplied to cough syrup manufacturers.

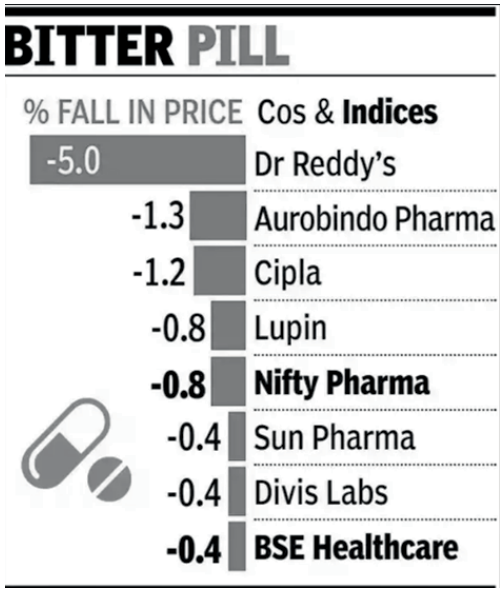
Source: *The Economic Times,* 9th December 2023

Pharma Faces USFDA Heat, Stocks Down

At a time when sensex and Nifty have been scaling new highs, the stocks of several Pharma companies have been lagging behind.

BSE sensex crossed the 70K mark for the first time but Dr Reddy's scrip fell nearly 7% in early trading hours before closing nearly 5% down at Rs 5,473 as against previous session's closing of Rs 5764.

Dr Reddy's scrip took a hammering after a stock broking firm raised red flag over possibility of US Food & Drug Administration's (USFDA) observations on its formulations facility FTO-3 at Bachupally in Hyderabad translating into a warning letter. The facility was inspected by USFDA in October this year and received Form 483 with 10 observations. As per reports, these observations included lack of proper cleaning of utensils and equipment, failure to explain unexplained discrepancies, usage of instruments and apparatus that do not meet specifications, ill-maintained buildings where manufacturing of drugs takes place, among others.



The scrips of other Pharma biggies such as Aurobindo Pharma (-1.3%) Cipla (-1.2%), Lupin (-0.8%), Sun Pharma (-0.4%), Divi's Labs (-0.4%) too closed in red on Monday even as Pharma sector indices - Nifty Pharma and BSE Healthcare - closed 0.8% down and 0.4% lower, respectively. Analysts and experts attributed the sectoral downtrend to the regulatory heat that several Indian generics manufacturers have been facing lately from the USFDA, which has stepped up inspections of manufacturing facilities post Covid-19. "The sensex and overall markets have been doing well because of the certainty of the Modi government continuing for five more years but sectors like Pharma are not doing well due to regulatory challenges," said V S Vasudevan, a Pharma industry veteran.

Rashmi Shetty, Pharma analyst, Daulat Capital, feels that other issues such as a "not-too-great" domestic sales data and profit-booking could be dragging Pharma stocks down.operational; quality; environment, health, and safety (EHS); and technical parameters. This will significantly reduce the transaction time and the time-to-onboard a CMO. We estimate the reduction in the total transaction and onboarding time to be 50% - 75%. The platform can also provide additional services such as performing quality checks of the CMOs while they are onboarded, and contract management services.

Source: *The Times of India, 12*th December 2023

Health Minister Says Comments from Stakeholders Considered and Incorporated in the New Bill

Even as the medical devices industry in the country has been demanding a separate regulation and a department for the medical devices as against the proposed inclusion of provisions in the draft New Drugs, Medical Devices and Cosmetics Bill, 2023, the Union ministry of health and family welfare (MoHFW) has said that it has considered and incorporated the comments from the stakeholders in the Bill.

Responding to a question by the Member of Parliament A D Singh in the Rajya Sabha, Minister of State in the MoHFW Dr Bharati Pravin Pawar said, "Comments and inputs have been received from various

stakeholders on the draft Drugs, Medical Devices and Cosmetics Bill, 2023 which had been published for public consultation. These have been considered and incorporated."

The Member of Parliament sought response from the Ministry on whether there is consistent demand by the industry to frame a separate law for medical devices and if so, the response of the Government.

Pawar responded that as per Section 3(b) of the Drugs and Cosmetics Act 1940, drugs include "such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central government".

The medical devices industry in the country has been raising concerns that its inputs to the draft Bill has been overlooked by the Ministry even after the Department-related Parliamentary Committee backed their demand for a separate regulation and department for the segment, which is different from the drugs and cosmetics segments.

The Association of Indian Medical Device Industry (AIMED) has recently said that despite its consultations with the Ministry, the key issues such as regulatory complexities, the potential impact on innovation, and the need for a conducive business environment have yet to be adequately assured by redressal in the bill. The lack of alignment with industry expectations has raised fears of stifling growth and hindering technological advancements in the medical device sector and continued import dependence as easier to import high end medical devices than to get regulatory approval for domestic manufacturers, they said.

AIMED Forum Coordinator Rajiv Nath, while expressing his disappointment, said that even after the assurance given by Union minister of health and family welfare, and chemicals and fertilizers Dr Mansukh Mandaviya, no committee was formed to review the different tenets of the Bill on a clause-by-clause discussion to align it or as suggested to use earlier separate Bill drafted by NITI Aayog in 2019.

"The need of the hour is a progressive modern separate law for addressing patient safety concerns. NITI Aayog had drafted an excellent Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 but in vain and we keep going in circles. Who gains from putting Indian manufacturers at a disadvantage over imports and by Drug pharmacists weighing biased regulatory controls? Even the impactful recent progressive legislations in countries like Canada, UK, EU, Brazil, Malaysia, Singapore and Saudi Arabia were not studied. Who blocked that progressive visionary Bill?" asked Nath.

He added that by keeping a chapter of penalties and punitive actions common with drugs, we are only reviving the Inspector Raj, which the nation cannot afford as we are working hard to make India self-reliant by

promoting the 'Make India' spirit as envisioned by Prime Minister Narendra Modi.

"We need competent auditors from engineering and science background and not dominant pharmacists with expertise of Drugs applying their drug regulatory inspection-based knowledge on medical devices that cannot have guarantee of absolute safety and are seeking an overkill. Discussing the potential impact of the Bill, which appears to favor foreign players," said Dr. Giridhar Gyani, Director General of the Association of Healthcare Providers India (AHPI).

He emphasized, that in the national interest, it is crucial for us to highlight that if the Bill is passed as is, the healthcare providers sector, heavily reliant on medical devices and advocating for increased availability of affordable, high-quality, made-in-India medical devices, may once again face challenges in management of supply chain, leading to crisis and country wide lockdown similar to the onset of Covid. Domestic manufacturers might lose their capacity to swiftly address domestic demand, especially in the event of a pandemic.

Source: *Pharmabiz,* 20th December 2023

70% of Admitted Patients Given Antibiotics

Nearly 7 out of 10 admitted patients are prescribed antibiotics, a survey carried out in 20 public hospitals across the country has revealed.

A survey carried out in 20 public hospitals across the country has revealed that 72% in-patients are prescribed antibiotics, with 5% patients getting four or more antibiotics. More importantly, the survey carried out by the National Centre for Disease Control (NCDC) showed that watch group antibiotics (antibiotics that have higher resistance potential) were prescribed more frequently compared to access group antibiotics (antibiotics with lower resistance potential).
The World Health Organisation had, in 2019, classified 180 commonly used antibiotics into three categories namely, watch group antibiotics, access group antibiotics and reserve group antibiotics (antibiotics and antibiotic classes that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms) to emphasise the importance of their optimal uses and potential for antimicrobial resistance.

The UN health agency also listed antibiotics whose use is not recommended - namely fixed-dose combinations of multiple broad-spectrum antibiotics that lack evidence-based indications for use or recommendations in high-quality international guidelines.

According to the survey, one of the largest multi-centre PPS (Point-Prevalence Survey) conducted in the country till date to assess antibiotic usage, many institutions prescribed antibiotics that come under the not-recommended group as per WHO.

"Only two sites reported higher prescription rate for access group antibiotics," the survey found. The survey report was released by

Union health minister Mansukh Mandaviya. It recommends that institutions should keep the consumption of reserve group antibiotics at low levels.

"Poly pharmacy (simultaneous use of multiple medicines) was observed in all the institutions. Combining two antibiotics can increase the risk of adverse effects and drug interactions," the report says.

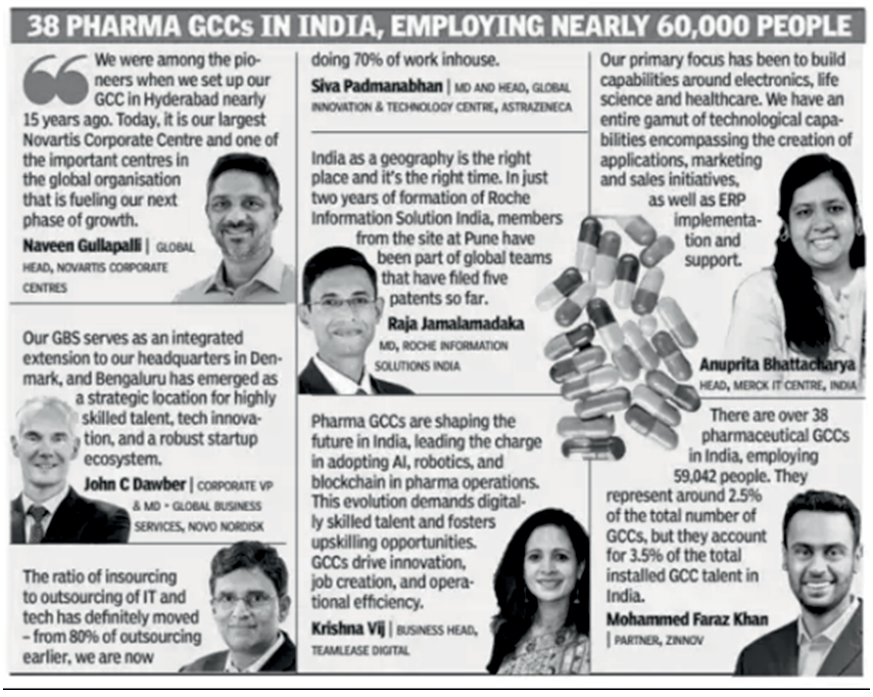
Source: *The Times of India,* 3rd January 2024

From Pharmacy of World, India Moves to Innovation in Pharma

No longer is India just the 'pharmacy of the world', manufacturing and exporting bulk drugs and affordable generic medicines, it is also now rapidly emerging as a hub of Pharma innovation and digitisation, as global Pharma giants home in on India for their global capability centres (GCCs).

Be it mature GCCs of Danish giant Novo Nordisk and Swiss behemoth Novartis, which came up over 15 years ago, or younger ones like Roche, big pharma is counting on Indian talent to drive future growth.

The centres here support global functions such as clinical trials, pharmacovigilance and drug safety, and regulatory drug filings. They chip in with drug discovery and help the parent companies leverage emerging technologies such as Gen AI, AR/VR, and IoT.



Novo Nordisk's blockbuster weight loss and type-2 diabetes drug Semaglutide, which sells under the brand names Wegovy and Ozempic, respectively, was supported by its Bengaluru-based global business services (GBS) centre. The GBS provides analytical and technology support to get a drug to market through preclinical trials' analytics and data collation for regulatory submissions.

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The Novartis Corporate Centres (NOCC), which was set up in Hyderabad around the same time, today houses over 8,100 associates, making Hyderabad its single largest location outside HQ Basel. While NOCC provides support services across drug development, business services, data, digital & IT, manufacturing, HR, finance, legal and more, the Novartis Development Operations Organisation, located in Hy derabad and Mumbai, caters to all the company's global functions – clinical operations, technical R&D, patient safety & pharmacovigilance, and regulatory matters. The latter houses 3,000 of the 12,000 global development employees and has been an integral part of the development of several breakthrough medicines in cardiovascular, oncology, immunology, neurology and ophthalmology, a Novartis spokesperson says.

AstraZeneca has over 3,100 employees across its Global Innovation and Technology Centre (GITC) in Chennai and R&D centre in Ben galuru. GITC hosts over 50% of the group's technology operations.

AstraZeneca's India centres work on Gen AI applications such as copilot tools that answer FAQs on rare diseases, and on immersive technologies that train shop floor operators and which physicians use to understand how new drugs work. “The focus is on automation, so that we can free up our teams to work on futuristic solutions,” says Siva Padmanabhan, MD & head, GITC.

Merck has three centres of excellence (CoEs) – shared business services CoE set up in 2011, Merck IT Centre (2018) and Healthcare R&D (2021) – with a total of around 2,500 people in Bengaluru.

Anuprita Bhattacharya, head of Merck IT Centre, India, says they were the first in the industry to develop an in-house app called myGPT in less than 45 days after ChatGPT came out. “myGPT is secure and capable of doing certain Merck-related research,” she says. The centre here also developed mySite, a mobile and web application that has helped resolve over 55,134 observations by Merck's 75 participating sites across 12 countries.

Merck's Healthcare R&D CoE caters to seven key global functions. “We are evolving into a true global hub. One day we will see

end-to-end functions being run from India," says Suneela Thatte, VP & head, Healthcare R&D India at Merck.

Roche Information Solutions India, set up in November 2021, has already grown to a team of around 350 in Pune. Raja Jamalamadaka, MD, says they develop software and data analytics solutions for personalised healthcare. "We also do endto-end implementation of a particular digital product," he says.

Capabilities grow faster than headcount

Most of the GCCs are rapidly stepping up their India headcounts. Novo Nordisk expects headcount in Bengaluru to exceed 4,000 this year. "In 2023, we would have created around 700 new roles and anticipate a further 600 new roles in 2024. What was a volume and scale-based set-up has now become a skill-based centre heavily focused on innovation," says Dawber of Novo Nordisk.

Padmanabhan of AstraZeneca says they have grown in headcount around 10-15% in the last two years, but capabilities have grown many fold. "We have made a commitment that any new technology we build will be centred in India and scaled to all markets from here," he says.

Source: *The Times of India,* 3rd January 2024

55% of Patients were Prescribed Antibiotics for Preventive Indications, 45% for Therapeutic Indications: NCDC Survey

Over half of the almost 10,000 hospital patients surveyed recently were given antibiotics to prevent infection, rather than to treat it, amidst growing concerns about the rise in resistance to antibiotics. The vast majority of patients surveyed – 94% – were given antibiotics before the confirmation of a definitive medical diagnosis of the precise cause of infection.

Earlier this week, the Health Ministry released the results of a survey conducted by the National Centre for Disease Control, mapping the patients treated on one to five days each at 20 tertiary care institutes across 15 States and two Union Territories between November 2021 and April 2022.

Out of 11,588 admissions and 9,652 eligible patients, 72% were prescribed antibiotics. Of these, only 45% were prescribed antibiotics for therapeutic indications, meant to treat infection or disease. The remaining 55% were prescribed the drugs for prophylactic indications, meant to prevent the occurrence or spread of an infection. Only 6% were prescribed antibiotics after a confirmed diagnosis of the specific bacteria causing their illness, called definitive therapy. The remaining 94% were on empirical therapy, based on the doctor's clinical experience in assessing the likely cause of an illness.

Growing resistance to antibiotics

The World Health Organization (WHO) has

identified antimicrobial resistance (AMR) as one of the top threats to public health. It is a natural phenomenon as bacteria evolve, making drugs used to treat infections less effective.

However, as the NCDC survey notes, one of the main drivers for the development of antibiotic resistance is the excessive and inappropriate use of antibiotics.

To deal with the challenge of limited information on how antibiotics are prescribed and used at the patient level, WHO has introduced the global point prevalence survey methodology to understand the prescribing patterns in hospitals, with repeated surveys showing the changes in antibiotic use over time. Few studies have been conducted in India using this methodology.

Differences among hospitals

The NCDC survey report noted wide variations between the different hospitals, with some prescribing antibiotics to 37% of patients, while the prevalence was 100% in other institutes.

Overall, there were 12,342 antibiotic prescriptions, with 86.5% of these prescribed through the parenteral route, meaning that they were not taken orally.

Using the WHO's Access, Watch and Reserve (AWaRe) classification, it was found that only 38% of the prescriptions were for antibiotics belonging to the Access group, which "offer the best therapeutic value, while minimizing the potential for resistance". However, a much larger 57% of the prescriptions were for antibiotics belonging to the Watch group, which are "only indicated for specific, limited number of infective syndromes and are more prone to be a target of antibiotic resistance". Just 2% of the antibiotics prescribed were from the "last resort" Reserve group of drugs.

"About 3% of the prescriptions were of the 'not recommended' group. The high use of Watch group antibiotics is of concern as these antibiotics have a higher potential to develop antibiotic resistance," the survey noted.

Tracking antibiotic use

The NCDC is the nodal agency for India's national programme on AMR containment, of which one of the key components is the surveillance of antibiotic usage. To achieve this goal, it has established the National Antibiotic Consumption Network (NAC-NET) through which network sites compile data on antibiotic consumption in their respective health facilities and send it to NCDC.

According to NCDC, a major contributing factor to antibiotic resistance is the overuse of antibiotics by humans, with approximately half or more hospitals using antibiotics inappropriately.

Source: *The Hindu,* 3rd January 2024

New Antibiotic Identified to Target A Drug-Resistant Bacterium

Researchers have identified a new class of antibiotics with the potential to tackle a drug-resistant bacterium, Acinetobacter baumannii. Zosurabalpin was found to be effective against CRAB (carbapenem-resistant Acinetobacter baumannii)-induced pneumonia and sepsis in mouse models.

Writing in Nature, Zampaloni et al and Pahil et al reported the identification and analysis of the antibiotic zosurabalpin that can kill Acinetobacter baumannii, antibiotic-resistant strains of which are hard to treat in the clinic. Dr. Zampaloni and colleagues identified a tethered macrocyclic peptide (MCP) that selectively kills A. baumannii. The compound was further optimised for efficacy and tolerability, and the fine-tuning culminated in zosurabalpin, a drug candidate.

In an article, Morgan K. Gugger and Paul J. Hergenrother, Department of Chemistry, University of Illinois at Urbana-Champaign wrote that copious evidence provided by Zampaloni et al indicates that the antibiotic kills A. baumannii through a previously unknown mode of action. It inhibits a key process, transport of the molecule lipopolysaccharide (LPS), by inhibiting a complex of proteins. This complex was essential for transporting LPS to the bacterial surface to create the outer-membrane structure of Gram-negative bacteria. Zosurabalpin blocks LPS transport, and the abnormal build-up of LPS in the cell kills the bacterium.

"It was effective against more than 100 CRAB clinical samples tested in the laboratory and it considerably reduced the levels of bacteria in mice with CRAB-induced pneumonia and prevented the death of mice with a CRAB-induced abnormal immune response called sepsis," the article said. The antibiotic has been evaluated in two phase I clinical trials.

Source: *The Hindu,* 4th January 2024

Blood Not For Sale, Charge Processing Cost Only, DCGI Tells Blood Banks

The Drugs Controller General of India on Thursday banned all charges on blood units, except supply and processing costs. DCGI has sent out a letter stating this to drug controller cum licensing authorities in all states and Union territories.

Referring to the meeting of Drugs Consultative Committee held in September last year, DCGI wrote, "It was recommended with respect of agenda No. 18 of ATR point 3, for overcharging of blood, it was opined that blood is not for sale, it is only for supply and only processing cost may be charged by a blood centre."

DCGI has also asked the drug controller cum licensing authorities to direct all blood centres to adhere to the revised guidelines for recovery of processing charges.

When a person donates blood, it is not transfused into a patient directly. The donated

blood, referred to as whole blood, is processed in centrifuges to separate it into transfusable components. This includes red cells, platelets and plasma. The exercise is referred to as blood processing and a cost is incurred on this.

To standardise charges and put a cap on it, Centre released a guideline in 2022 stating that private blood banks cannot charge more than Rs 1,550 for processing whole blood. Processing charges for packed red cells, fresh frozen plasma, and platelet concentrate — all of which are required for transfusion in patients — have been capped at Rs 1,550, Rs 400, Rs 400 respectively for private labs. In government-run blood centres, the cost of processing whole blood and packed red cells have been capped at Rs 1,100.

Source: *The Times of India,* 5th January 2024

Sale of Generic Versions of Cancer Drug Stops as Delhi HC Prohibits Patent Infringement

Sale of generic versions of cancer medication Ibrutinib, used to treat leukaemia, has been blocked across the country, denying patients access to affordable therapy.

The Delhi high court recently passed an injunction against six domestic companies Natco Pharma, Hetero, BDR Pharma, Shilpa Medicare, Alkem and Laurus Labs from marketing generic versions. The order was passed on grounds of an infringement of the drug's patent. The Ibrutinib patent is held by Pharmacyclics, a subsidiary of US firm AbbVie, while the drug is marketed in the country by Johnson & Johnson, an Indian affiliate of Janssen Biotech.

The Ibrutinib patent is valid till 2026, and it is commercially sold under the registered trademark, Imbruvica.

"The fact that the defendants are in fact manufacturing and selling Ibrutinib, without a licence from the plaintiffs, is not disputed. Where a granted patent is prima facie found to be infringed, and is being exploited without a license from the patent holder, the balance of convenience is always in favour of restraining further infringement. I am aware that the drug in question is needed for treating various serious ailments, including cancer. That said, the law sternly prohibits patent infringement, and it may not be possible to argue that considerations of public interest should be allowed to justify infringing drugs to circulate in the market," Justice C Hari Shankar, said in an order, a copy of which was accessed by TOI.

This is a batch of six suits and one writ petition. The writ petition, filed by Laurus Labs in a post-grant application challenged the patent granted to the US firm before the Indian Patent Office, and sought its revocation.

Given the importance of the drug, however, the court permitted companies to exhaust the stock available with them, subject to their placing, on affidavit with this court with the details of sales.

Source: *TThe Times of India,* 10th January 2024

Health Ministry Notifies Revised Pharma Manufacturing Rules Under Schedule M to Ensure Quality Control

Aimed at ensuring robust quality control for pharma and biopharmaceutical products, the Union Health Ministry on January 6 notified revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945.

Schedule M prescribes the Good Manufacturing Practices (GMP) for pharmaceutical products and the revised Schedule M has been notified as rules to ensure GMP is adhered to, and requirements of premises, plant, and equipment for pharmaceutical products.

GMP is mandatory standards which builds and brings quality into a product by way of control on materials, methods, machines, processes, personnel, and facility/environment, etc. GMP was first incorporated in Schedule M of the Drugs and Cosmetics Rules, 1945 in the year 1988 and the last amendment was done in June, 2005.

With the amendment, the words 'Good Manufacturing Practices' (GMP) has been replaced with 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products'.

'On par with global benchmark'

"To keep pace with fast-changing manufacturing and quality domain, there was a necessity to revisit and revise the principles and concept of GMP mentioned in current Schedule M. This would bring our GMP recommendations at par with global standards, especially to those of World Health Organization (WHO), and ensure production of globally acceptable quality of drug," said a senior Health Ministry official about the recent move.

The changes introduced in the revised Schedule M include introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.

The notification, dated December 28, 2023 states that manufacturers must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the licence, and do not place patients at risk due to inadequate safety, quality, or efficacy.

It adds that companies must market a finished product only after getting "satisfactory results" on tests of the ingredients and retain a sufficient quantity of the samples of intermediate and final products to allow repeated testing or verification of a batch.

Speaking about the revision, Sudarshan Jain, secretary general, Indian Pharmaceutical Alliance (IPA) said, "The revision of Schedule M by the government is a positive step and an important milestone for

the Indian pharmaceutical sector. This will elevate and update the quality standards of medicines, reinforcing the reputation of our industry and improving patient outcomes. We welcome this initiative helping India's journey to become a global benchmark in quality."

"The revised regulations of Schedule M will help ensure compliance with international quality standards and will benefit both patients and the industry by promoting the manufacturing of safe, effective, and high-quality drugs. The focus on risk management, qualification and validation of equipment, and self-inspection will be vital contributions."

Earlier in August, the Ministry had set a six-month deadline for small manufacturers and 12 months for large units to get their World Health Organization-Good Manufacturing Practices (WHO-GMP) certification.

The revised rules is to be implemented on the basis of company turnovers where the medium and small manufacturers include those with an annual turnover of less than ₹250 crore who will have to implement the revised rules within 12 months from its date of publication, whereas large manufacturers with an annual turnover of over ₹250 crore will be given six months to do so.

The revised Schedule M has 13 parts which provide GMP guidelines for the specific requirements for manufacturing pharmaceutical drugs. The revised rules has five new categories of drugs including pharmaceutical products containing hazardous substances such as sex hormones, steroids (anabolic and androgenic), cytotoxic substances, biological products and radio pharmaceuticals.

Source: *The Hindu,* 6th January 2024

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