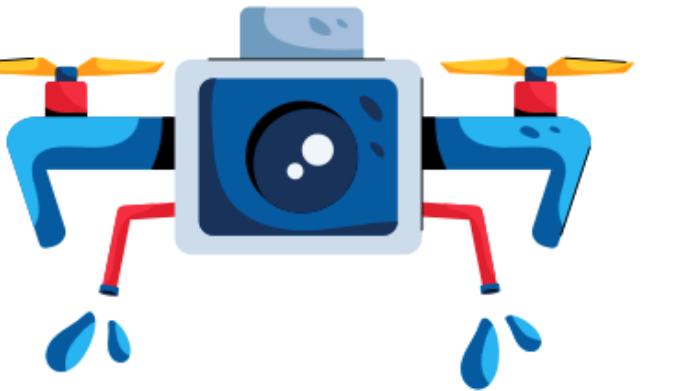




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KNOWLEDGE . LEADERSHIP

Agri Science Analysis Report

A comprehensive look at the agriculture industry,
focusing on Regulatory Process Analysis &
Recommendation for Improvement



Know the **TEAM!**



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Index

- Company Process
- Purpose
- Task and Activities
- Existing Process
- Process Analysis
- New Proposed Process
- Efficiency and Effectiveness



Overview of Company



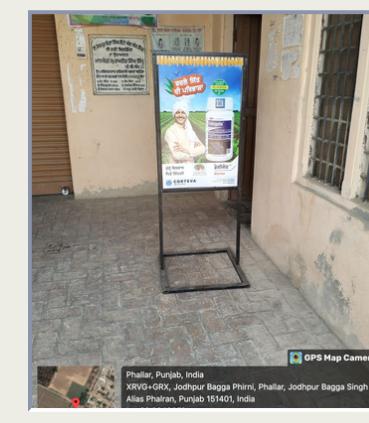
Agriscience company offers farmers around the world the most complete portfolio in the industry with a balanced and globally diverse mix of seed, crop protection, and digital innovation. These solutions are focused on maximizing productivity while generating advantaged market preference through the company's unique distribution strategy.

Purpose

To enrich the lives of those who produce and those who consume, ensuring progress for generations to come.

Our winning aspiration

To be the leader of innovation sustainable solutions for farmers worldwide, today and tomorrow...
to become the world's most valuable agriculture solutions company.



Process Description & Purpose

Regulatory & Stewardship (RAS)



Product Registration

Work with regulatory bodies such as FSSAI, CIB&RC, and ICAR to get approval for new Product

Regulatory Compliance

Ensure appropriate packaging, labeling, and legal certification.

Environmental Stewardship

Promotes sustainable agricultural practices to minimize environmental impact and support biodiversity.

Quality Validation

Ensures that all regulatory requirements, safety, efficacy, and legal obligations are met before the product can be marketed.

List of task

Dossier Preparation and Submission (1-2 Months)

Compiling the data, reports, and studies into a dossier for submission to regulatory bodies.



Regulatory Studies (18-24 Months)

This is the longest phase, involving comprehensive scientific studies related to bio-efficacy, plant and soil residues, shelf life, toxicology, transport worthiness, etc.

Approval by Registration Committee (1 Month)

Official approval of the dossier by the regulatory body, clearing the product for market consideration.



Dossier Review (3-8 Months)

A detailed review by the regulatory committee will be conducted, covering legal, bio-efficacy, chemistry, toxicology, and packaging aspects.

Authentication by CIB&RC (1.5-2 Months)

Authentication of product labeling, leaflets, and issuance of certificates, ensuring proper documentation for marketing the product.



FSSAI MRL Fixation & Minutes Issuance (1 Month)

Setting the Maximum Residue Limit (MRL) by FSSAI and recording minutes for future reference.

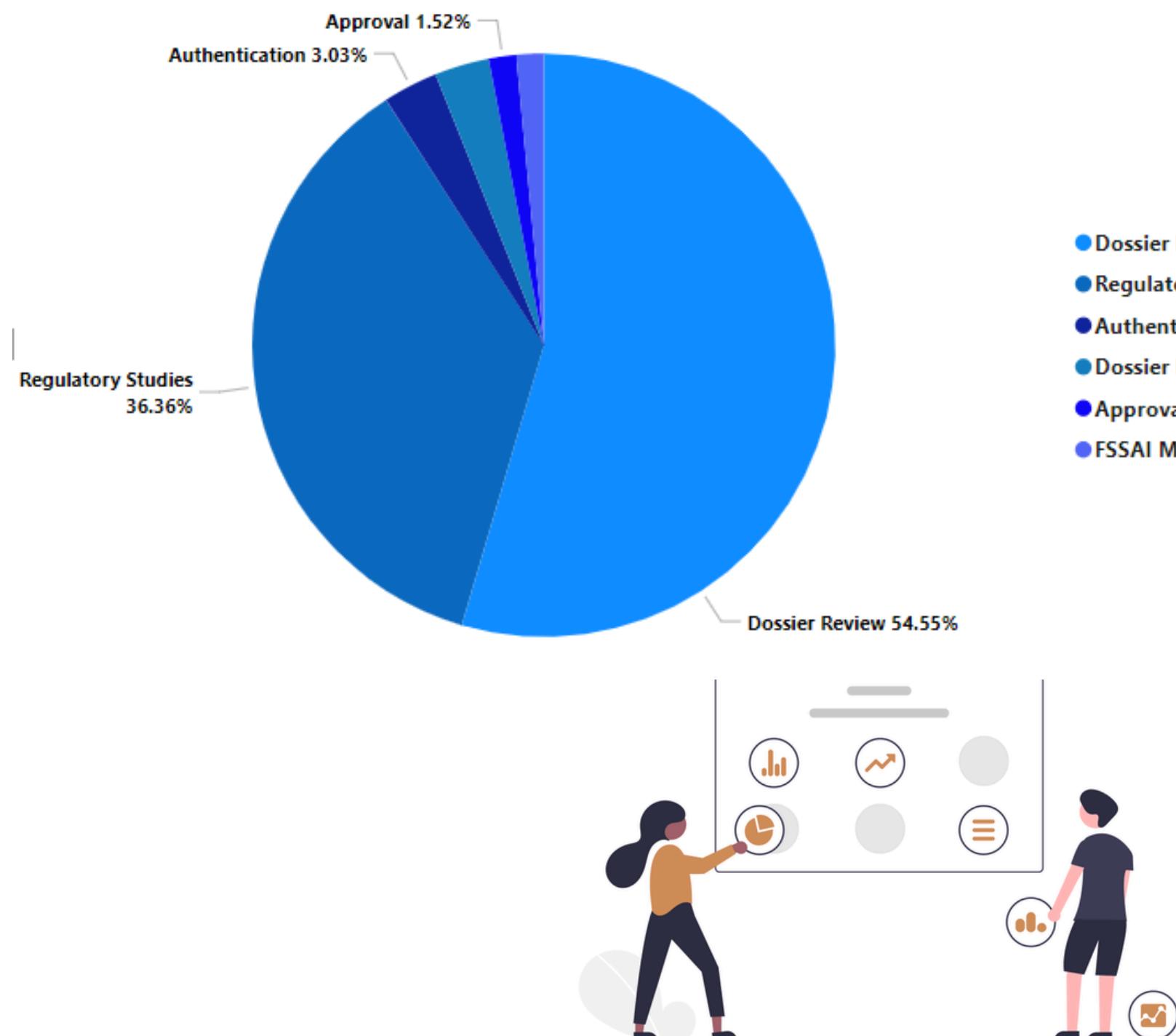


Certificate in Hand

Final issuance of the certificate, signaling the end of the process and official clearance to market the product.

Key Metrics

Existing Regulatory system



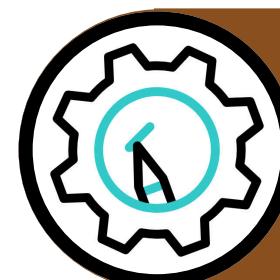
Insights related to the regulatory approval Process for new molecules, highlighting time, capacity, and bottlenecks."

- Throughput Time: 68 months
- Cycle Time: 38 months
- Bottleneck: Dossier Review (38 months)
- Total Capacity per shift : The working days are 20 per month, and with dossier review as the bottleneck, the total capacity per shift is 16 units (calculated as $20 \times (1/38) \times 30$)
- Average work time in Days: Process Work time is Cycle time* Capacity . Total work time is 54. Average work time is $54/6=9$
- Average idle time in days: Process Idle time is the Number of days in a month-Work time. Total Idle time is 126 . The average idle time is $126/6 = 21$
- Idle time in days: Time when the process is waiting for another task = Total Idle time / Total Number of days *100 = $(126/180)*100 = 72$
- Capacity Utilization: Total utilized capacity = 100/Total utilization *Work time = $100/180*54 = 30$



Regulatory Process

From Current to Future: Process Improvement Analysis



Current Process

Parallelization

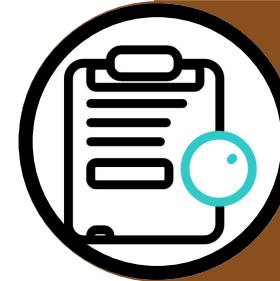
Single-threaded process

Automation

Manual reviews, approvals causing delays

Resource Allocation

Under-utilized resources during idle times

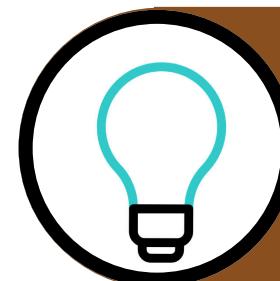


Proposed

Parallel paths for Dossier Review, FSSAI MRL, and Authentication

Automated dossier review and administrative tasks

Dynamic resource allocation across stages based on workload



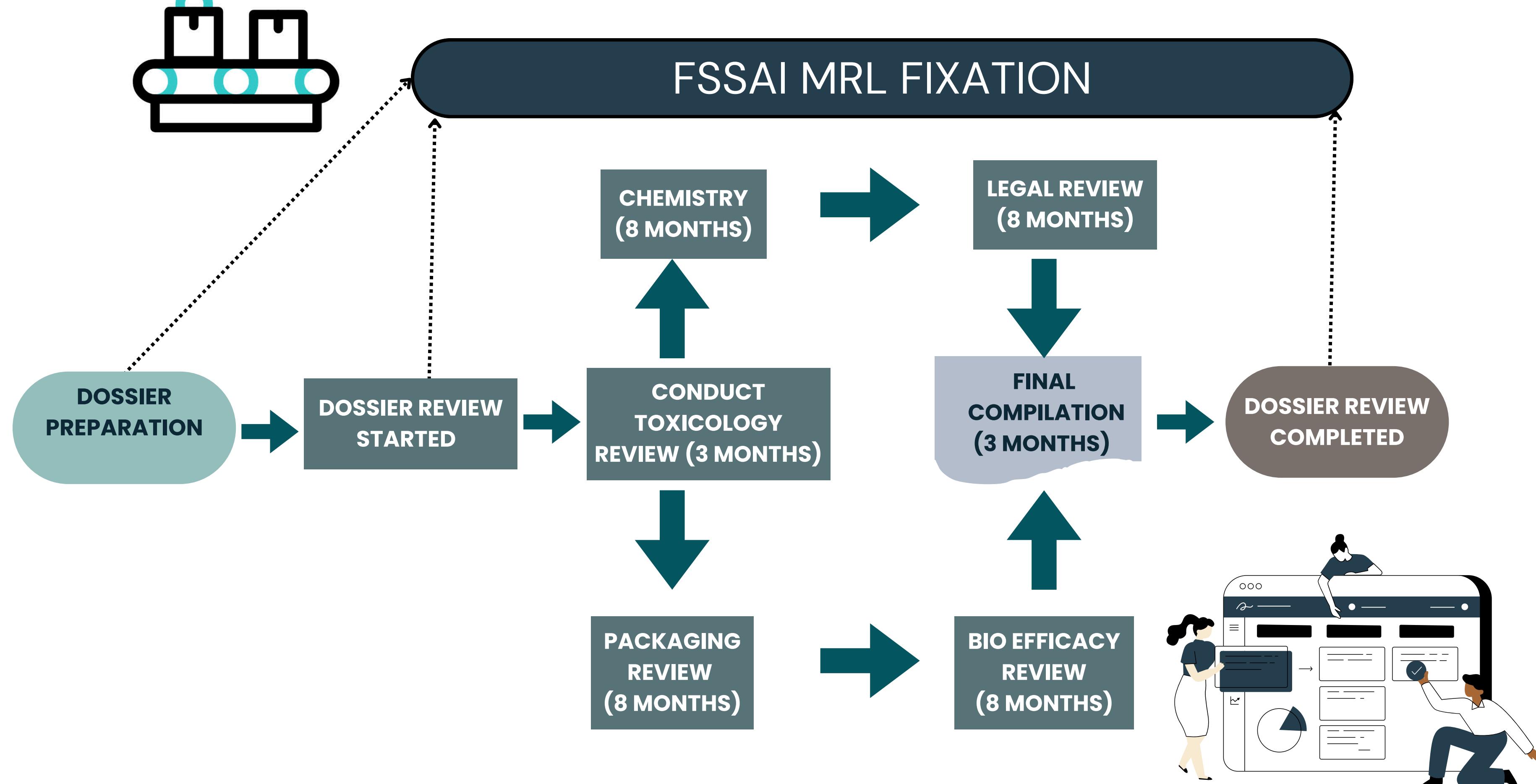
Impact

Increased capacity and reduced time-to-market

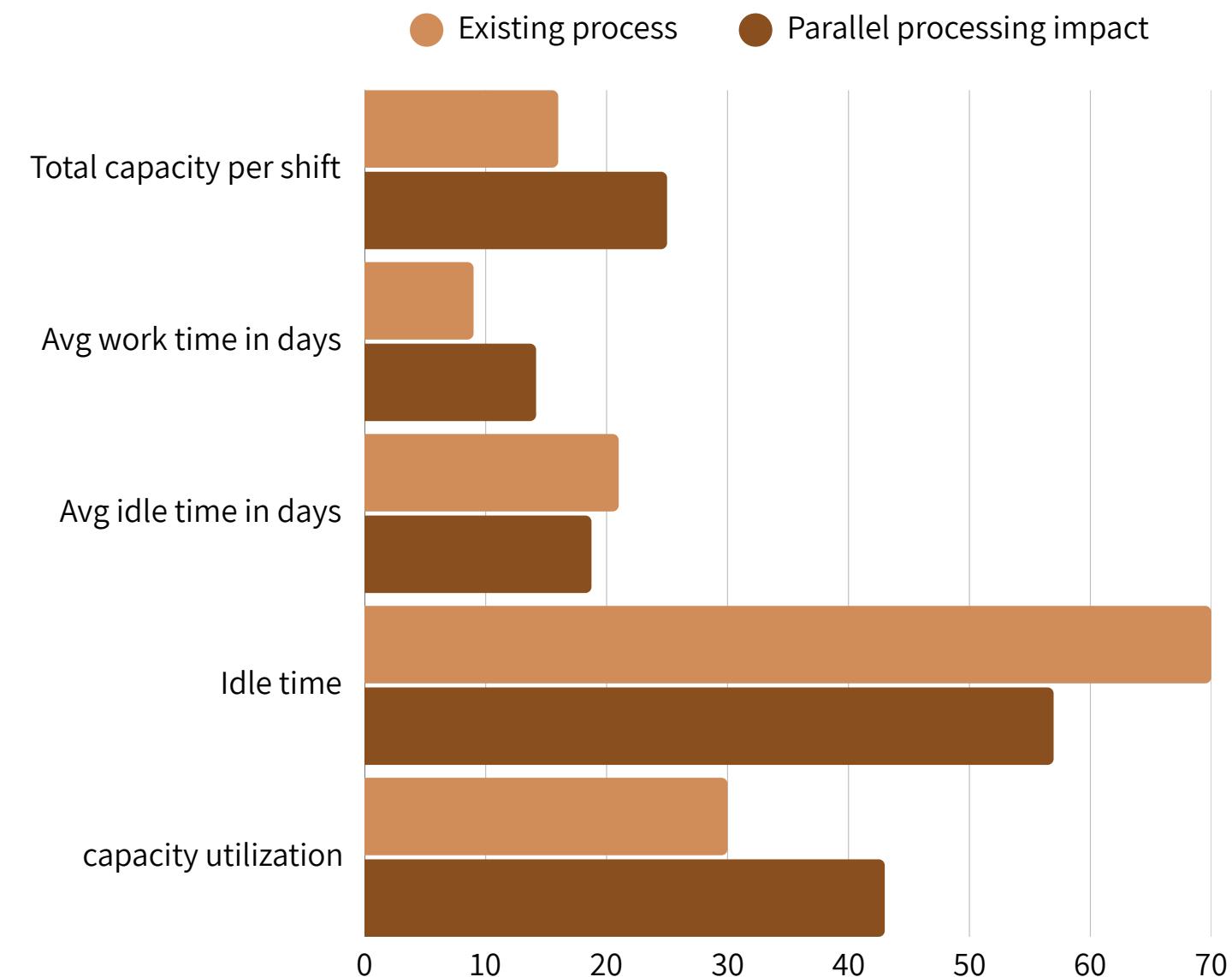
Reduced review time, fewer errors

Improved productivity, less idle time

Parallel Processing of Independent Tasks



Parallel Processing Impacts

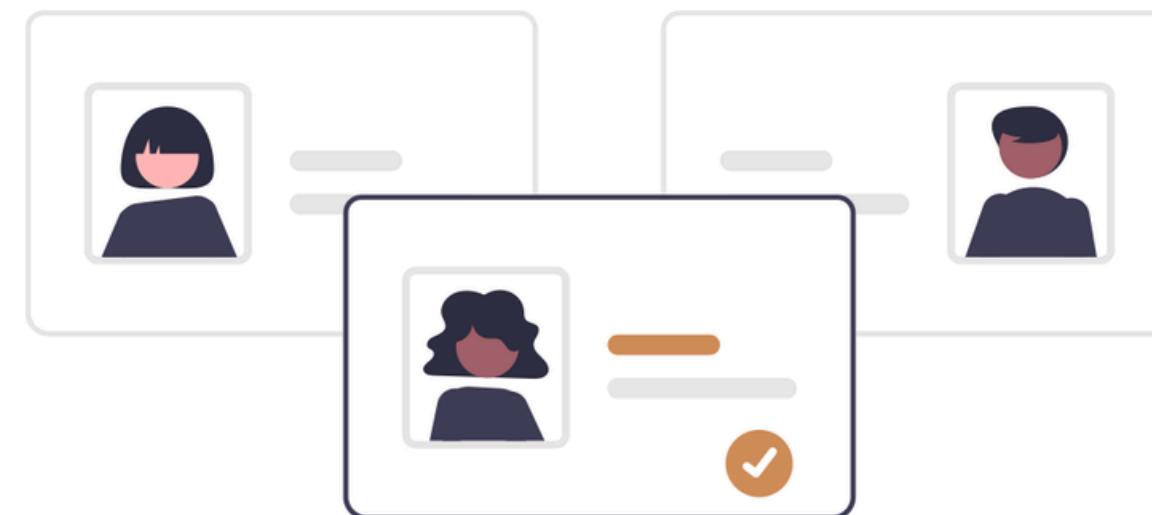


Insights

- Throughput time reduced from 68 months to 52 months
- Bottleneck and cycle time reduced by 42%
- Total capacity per shift increased by 58.33%
- Average work time in days increased by 58.33%
- Average idle time in days decreased by 10.94%
- Idle time decreased by 18.83%
- Capacity utilization increased by 44.30%

New Process - Including parallel processing in Dossier Review Step						
Process	Cycle Time (Months/Unit)	Capacity (Unit/Days)	Capacity Utilization at Bottleneck Pacing (%)	Work time (Days)	Idle Time (Days)	Total
Regulatory Studies	24	1.25	100%	30.00	0.00	30
Dossier Preparation and Submission	2	15.00	8%	2.50	27.50	30
Dossier Review	19	1.58	79%	47.50	0.00	48
Approval by Registration Committee	1	30.00	4%	1.25	28.75	30
FSSAI MRL Fixation	1	30.00	4%	1.25	28.75	30
Authentication by CIB&RC	2	15.00	8%	2.50	27.50	30
TOTAL	49			85.00	112.50	197.5
Mean				14.17	18.75	

Increasing Resource Allocation

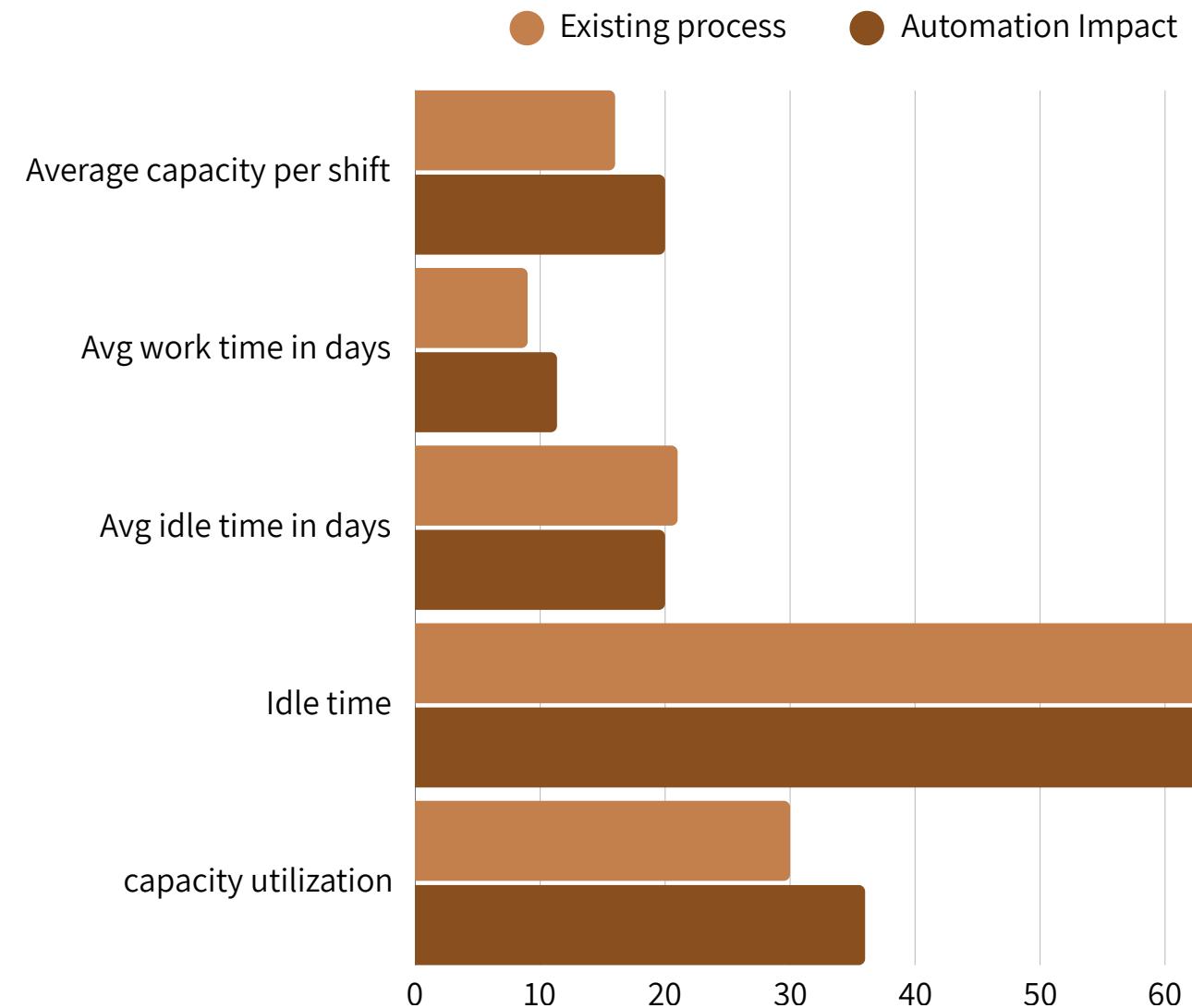


Insights

- Throughput time reduced from 68 months to 58 months
- Bottleneck and cycle time reduced by 25%
- Total capacity per shift increased by 35.71%
- Average work time in days increased by 35.87%
- Average idle time in days decreased by 6.70%
- Idle time decreased by 11.98%
- Capacity utilization increased by 28.18%

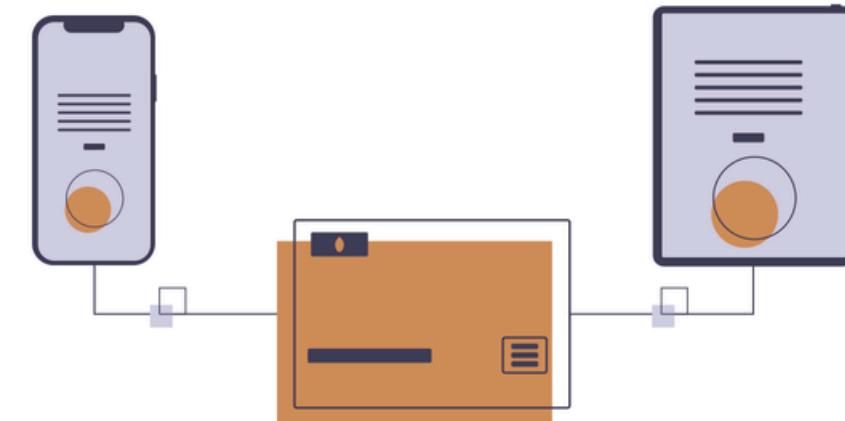
New Process - Increasing number of resources in the Dossier Review Step						
Process	Cycle Time (Months/Unit)	Capacity (Unit/Days)	Capacity Utilization at Bottleneck Pacing (%)	Work time (Days)	Idle Time (Days)	Total
Regulatory Studies	24	1.25	86%	25.71	4.29	30
Dossier Preparation and Submission	2	15.00	7%	2.14	27.86	30
Dossier Review	28	1.07	100%	40.80	0.00	41
Approval by Registration Committee	1	30.00	4%	1.07	28.93	30
FSSAI MRL Fixation	1	30.00	4%	1.07	28.93	30
Authentication by CIB&RC	2	15.00	7%	2.14	27.86	30
TOTAL	58			72.94	117.86	190.8
Mean				12.16	19.64	

Automation and Digital tools



Insights

- Throughput time reduced from 68 months to 60 months
- Bottleneck and cycle time reduced by 21%
- Total capacity per shift increased by 26.67%
- Average work time in days increased by 26.85%
- Average idle time in days decreased by 5%
- Idle time decreased by 9.09%
- Capacity utilization increased by 21.39%



New Process : Automation in the Dossier Review Step						
Process	Cycle Time (Months/Unit)	Capacity (Unit/Days)	Capacity Utilization at Bottleneck Pacing (%)	Work time (Days)	Idle Time (Days)	Total
Regulatory Studies	24	1.25	80%	24.00	6.00	30
Dossier Preparation and Submission	2	15.00	7%	2.00	28.00	30
Dossier Review	30	1.00	100%	38.10	0.00	38
Approval by Registration Committee	1	30.00	3%	1.00	29.00	30
FSSAI MRL Fixation	1	30.00	3%	1.00	29.00	30
Authentication by CIB&RC	2	15.00	7%	2.00	28.00	30
TOTAL	60			68.10	120.00	188.1
Mean				11.35	20.00	

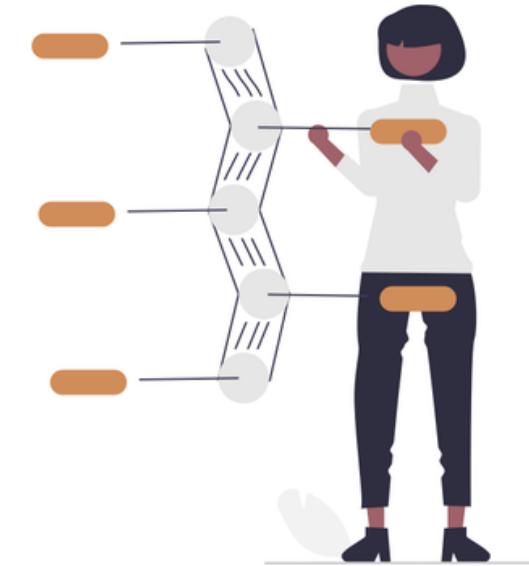
Conclusion

The existing registration process for new molecule formulations is crucial for ensuring regulatory compliance, safety, and efficacy. However, the process currently faces significant inefficiencies extending the 60-68-month timeline.

By implementing several targeted improvements, including:

- Parallel processing could help reduce the timeline by 20 months
- Automation, which could help in timeline reduction by 8 months
- Increasing resource allocation could help reduce the timeline by 10 months

The total timeline can be reduced to approximately 38-40 months.





Any questions?

Thank you!



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