STEP 01

RESPONSIBILITIES

- Spearheading Quality for pharmaceutical products.
- Provide a strategic direction for quality assurance, quality control and compliance activities for pharmaceutical products.
- Drive continuous improvement programs through internal operations including setting up processes for third party manufacturers.
- Supplier management including quality and compliance, audit, quality agreements and Relationship management.
- Overlooking Quality aspects of Product Commercialization

STEP 02

OBJECTIVES

- Increase Product Reputation by improving Product Quality standards.
- Protect brand reputation by assessing Product feedback and Performance
- Manage Batches Quality and maintain inventory with electronic signatures.
- Simplify Inventory Batch traceability and strengthen compliance reporting to simplify FDA audits.
- Track compliance for Product storage, manufacturing and Quality to avoid unnecessary risks with FDA.

QUALITY

STEP 03

PAIN POINTS

- Inability to do an instant electronic batch trace.
- Issues identifying paperwork attested with the right approvers.
- Cumbersome reporting making FDA audits challenging.
- Inability to identify patterns that fix processes proactively for the future.
- Inability to perform proper trending and analysis

STEP 04

THE RIGHT SYSTEM

- cGMP Compliant
- CFR 21 Part 11 Compliant
- Lot Inheritance and Batch traceability
- Electronic Signatures on key transactions
- Compliance reporting
- Quality Control and Quality Assurance records

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GET STARTED