

# Navigating Your GRC Journey

## Industry Experience Session (Case Study) Implementing a result oriented quality management Program

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# Agenda

1. Organization Overview: Vision and Key Facts
2. Organizational Structure: Lines of Business and Key Stakeholders
3. Business Challenge Identification: Top Challenges Facing Organization and Industry
4. GRC Program Objectives and Strategies
5. Overcoming Business Challenges
6. Technology as an Enabler
7. Successes and Benefits
8. Key Learnings and Best Practices
9. Audience Questions and Discussion

# Organization Structure

Global Clinical Quality Assurance (GCQA) reports directly to the Vice President RA, PV, CQA, in addition to a secondary reporting line to the Executive Vice President of Research & Development, in cases of dispute or other conflicting matters.

## Lundbeck's Lines of Business:

- Research and development organization - HQ
- Affiliates

## Key Stakeholder Identification:

- VPs in Research and development.
- IT Compliance
- Quality organisations.

# Organizational Overview

Lundbeck Global Clinical Quality Assurance Division is based out of corporate headquarters. Comprised of 14 auditors based in the 3 major regions. Are responsible for all clinical, pharmacovigilance and clinical computer system validation audit activities worldwide.

## Lundbeck GCQA's Vision:

- Provide the best Global Clinical Quality Assurance Services that exceeds the expectations of our internal and external customers
- Enhance the quality mindset by building quality from within.

## Key Facts about Lundbeck GCQA

- Operates globally supporting clinical trial activities in more than 70 countries in which Lundbeck operates.
- Provide quality assurance services for approx. 2000 customers worldwide.
- Conduct average 100 quality audits per annum.

# Business Challenges Faced

## Challenges related to People:

- Have to embrace and work through the change.
- Building new skills.

## Challenges related to Processes:

- Challenging the status quo - the way we've always done things.
- Move from manual paper based world to an electronic solution.

## Challenges related to Systems:

- First global system of its type to be rolled out.
- Limited experience as an organisation with eAM systems.
- Hosted solution - different way of supporting/servicing with patches, updates, new versions etc.

## Challenges related to Resources:

- Same operational staff involved in the implementation of the application.
- Balancing shifting priorities.

# GRC Program Objectives & Strategies

## Program Objectives:

- Full automation of the audit and CAPA lifecycle.
- Implement a platform that can be adopted by all audit units across Lundbeck.
- Improve on existing regulatory compliance.

## Program Strategies:

- Phased implementation approach
- Strategic partnership with the solution supplier.

## Role of Technology in Program:

- Eliminate manual processes.
- Increase transparency and availability of quality related data in the organisation.

# Overcoming Business Challenges

## Organization and Business Line Approach:

- Established steering committee and project team to govern activities.
- Involvement of representations across the whole business.

## Adopted Frameworks:

- Project activities broken down in workstreams, with distinct workstream charters.
- Current legislation and Lundbeck steering documents.

## Execution Methodologies:

- Internal project management methodology - reflects Prince 2.
- Change management.

# Technology as an Enabler

- MetricStream Solution Areas:
  - Simplified Risk Management
  - Audit Management Suite
  - CAPA Management
- Key Solution Functionality:
  - Simplified Risk Assessment of auditable entities
  - Audit Planning, Audit Conduct, Audit Reporting
  - CAPA Flow (Automation and follow up)
  - Audit and CAPA Metrics
- Implementation Strategy and Tactics:
  - Business Requirements Analysis and Workshops with MSI technical personnel
  - Functional Design Specification
  - Project Plan, Data Migration
  - Validation Strategy



# Successes and Benefits

## Success Metrics and KPIs:

- No critical or major observations from regulatory inspections or business partner's audits.
- Consistent and efficient automated audit processes and outputs

## Key Process Improvements and Efficiencies Gained:

- Simplification of the audit process.
- Single approach to CAPA management across the impacted lines of business.
- Reduce time taken to complete and audit end to end.
- Significant time saving to generate metrics and trend reports.

# Key Learnings and Best Practices

- Key Learnings:
  - Thorough and clear Requirements are key
  - Clear Communication
  - Working on site
- Best Practices:
  - Standard Solution
  - Change Management
  - Validation
- The Road Ahead:
  - Enhancements to usability of the system
  - More flexible, effective and dynamic reports and dashboards
  - Enhancement of system functionality (both for end users and admins)
  - Bring onboard the other deviation processes and other audit workflows.

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Thank You