

MetricStream

GRC

SUMMIT 2013

Apr 30 - May 1, 2013 | Mandarin Oriental, Las Vegas, NV



WELCOME



MetricStream GRC Summit 2013: Case Study

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Andria Rüscher

Divisional Director , Lundbeck

Quality Management Programs that Deliver Results

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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. Audit Objectives and Strategies
5. Overcoming Business Challenges
6. Technology as an Enabler (what drove us to make the decision to automate – business case)
7. Successes and Benefits
8. Key Learnings and Best Practices
9. Audience Questions and Discussion

Organization Overview

Lundbeck Global Clinical Quality Assurance Division is based out of corporate headquarters, in Denmark. Comprised of 12 auditors based in 6 countries around the world. Are responsible for all clinical audit activities the 3 major regions .

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 that 70 countries in which Lundbeck operates.
- Provides quality assurance services for approx. 2000 customers worldwide.
- Conduct average 100 quality audits per annum.

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GCQA reports directly to the Vice President of 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.

Business Challenges Faced

Challenges related to People:

- Have to embrace and work through the change.
- Develop 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 organization 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 and Strategies

Program Objectives:

- Full automation of the audit and CAPA process lifecycles.
- 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 organization.

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:**

- Audit Management suite
- CAPA
- Simplified Risk Management

- **Key Solution Functionality:**

- Audit Planning, Audit Execution workflow
- Audit reporting and Trending reports
- Alerts and notifications, Approval workflows.
- Corrective Action, Preventive Action
- Simplified risk assessment using standard factors – Impact and Likelihood.
- ADFS integration for user provisioning and authentication and Migration of legacy data, along with Archival feature.

- **Implementation Strategy and Tactics:**

- Early Analysis, Pre-requirements workshop with Metricstream Architect, GMP/GCP SME., Mapping business requirements to standard products.
- Established a effective Governance committee, Better quality and timely interactions at all levels.
- Conducted multiple walkthroughs for end users which helped create a better understanding of the MSI solution among the community.
- Data migration strategy –Better loading, search and retrieval along with reporting.
- Partnering together in the change management and training process. Partnered with customer to alter their internal processes to adapt with industry standard processes.
- Timely response and inputs into the project, Joint planning and sign-offs to contain scope creep etc.

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

Key Learnings and Best Practices

Key Learning's:

- Translating and Mapping user requirements to standard features and best practices in industry
- Hosted solution – made it easier and faster to implement since MSI had better access and control over the environment

Best Practices:

- More involvement and commitment from Lundbeck core team helped.
- Working closely on the system acceptance and managing change through effective communication
- Staying firmly on standard solution, still flexibly managing the varied requirements though configurations in platform in other GRC modules

The Road Ahead:

- Enhancements to solution, building more effective dashboards/insights.
- Deploying full-fledged ERM solution driving audit plans building on simplified risk
- Bring onboard the other deviation processes and other audit workflows.
- Product and platform upgrades – for new features and functionalities

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Questions and Discussion

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