ASQ Healthcare Division

4th Annual Healthcare Speakers’ Reception

Bayou E
Gaylord Opryland Resort and Convention Center, Nashville, TN
May 4, 2015
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4th Annual Healthcare Speakers’ Reception

• Mölnlycke Health Care
  *Silver Sponsor*

• Deborah Hopen Associates, Inc.
  *Bronze Sponsor*
2015 Sponsored Presentation

Javed Cheema, Fellow ASQ, CMQ/OE, CQE, CSSBB, CQA
Chief Engineer, Altarum Institute, West Bloomfield, Michigan

“Enhancing Total Patient Experience (TPE) in ERs”

Wednesday, May 6 at 9:15 in the Ryman Ballroom C
Nightingale Scholarship Award

presented to

Erin Van Landingham

for her winning essay on

“The Status of Geriatric Care in the United States: America’s Need for More Geriatricians”

on this day

May 4, 2015

ASQ Healthcare Division
The Global Voice of Quality™

William H. Dunwoody
HCD Chair

Tamara S. Lampro
Nightingale Scholarship Committee Chair
The **Collaborative Discipline of Daily Quality Compliance Management**

Romain Denis, RAQA Director
Mölnlycke Health Care
Presentation Outline

• Mölnlycke Introduction
• Quality System
• Succeed Process
• Succeed in the Future!
Mölnlycke Health Care

Introduction
Our Wound Care division provides health care professionals and patients with solutions that prevent, protect, and heal wounds.

- Dressings
- Negative pressure
- Electro-stimulation
- Compression
- Dermatology
Our **Surgical** division provides products and services to health care professionals in the operating room that improve **safety, efficiency, and clinical outcome.**

- Gloves
- Staff clothing
- Drapes
- Procedure trays
- Antiseptics
- Patient warming
Multi-National Corporation

Manufacturing sites
Sales office coverage
Global HQ and R&D hub
Quick facts

- **32** number of countries where we are present
- **98%** owned by Investor AB, remainder by management
- **1,153** annual global sales in MEUR (2013)
- **7,404** number of employees we have worldwide

Head office | Gothenburg, Sweden
Mölnlycke vision

Our passion for progress will make us the most trusted health care brand in the world.

Our core values

• Passion
• Learning
• Integrity
Mölnlycke value proposition

integrity  global  challenge  status quo  
people  learning  passion  trust  
grow  empowered  swedish heritage  
inovation  sustainable  family  
development  diversity  impact
Mölnlycke: Doing the Right Thing

As an international company, we have a particular duty to respect, promote, and comply with the principles of ethical and social responsibility.

Our Code of Conduct:
• Applies to all of our employees, and
• Applies also to our suppliers
Creating Value for our Customers

• We work to deliver innovative solutions that improve lives by:
  – Listening to patients and customers throughout product development
  – Evolving existing products to meet customer needs
  – Developing safe, cost-effective, and innovative products that are backed by good quality supporting evidence
  – Identifying ways to improve lives throughout the health care journey
Mölnlycke Health Care

Corporate Quality System
“Through excellence in regulatory, quality, and compliance, we will ensure that Mölnlycke Health Care’s brands are the most trusted in the world.”
### Some of the Major standards We Follow

<table>
<thead>
<tr>
<th>Category</th>
<th>Standard</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Directive</td>
<td>MDD 2007/47/EC</td>
<td>We also adhere to FDA and more than 400 applicable local rules, regulations, and requirements.</td>
</tr>
<tr>
<td>Environmental Management</td>
<td>ISO 14001:2004</td>
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<tr>
<td>Health &amp; Safety</td>
<td>OHSAS 18001:2007</td>
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<tr>
<td></td>
<td>ISO 13485:2012 and CMDCAS</td>
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Mölnlycke Health Care

Succeed Process
What is it and why? Is it developed only for compliance?

“To be able work together as effectively and efficiently as possible to meet customer expectations”

Facilitates the shared “Worker’s View” of daily management!
What Is Daily Management?

• A process for **Dynamically** administering the routine work of an organization in order to
  – Comply with all external regulations
  – Perform internal procedures
  – Achieve the requirements and expectations of customers

• Combines a **Discipline** of compliance to regulations
  – Documented work procedures
  – Continual improvement of work activities
  – Skills development to increase efficiency and cost-effectiveness of all processes
What Is Daily Management?

• To succeed in **Daily** management requires
  – Processes be properly documented
  – Measures be accurately reported on the status of work progress
  – Performance be monitored, reviewed, and reported
    • Reporting conducted with integrity to assure that the status of performance is visibly evident to senior managers
    • The system anticipates all needs of decision makers for information to guide overall direction.
Design Principles of the Succeed System

- **Process orientation**: What, How, When and Who
- **Accountability**: person executing is owning the process (compliant, effective, efficient and training)
- **Communication** tool and user orientation
- **Operating control** and quality assurance
- **External requirements Compliance**: we are required to meet 400 regulations
How do we assure that we will **Succeed**?

The daily management system **MUST** be **designed** so that it is able to **comprehend and respond** to all the diverse requirements that the medical device and pharmaceutical industry requires in all countries in which Mölnycke operates.

These requirements **MUST** be **integrated** and aligned in both the operational and geographic dimensions of the organization in order to assure that a **collaborative process** of daily compliance management is first established and then maintained.

Maintenance of currency of these comprehensive requirements and alerting to changes **MUST** be **automated** and **communicated** to assure the dynamic environment of regulatory change is kept in a state of document control that assures the **best opportunity** for company-wide compliance.
Process Owner

Provides managerial leadership to ensure that the process runs effectively and that capabilities and competence have been developed so that organizational units can efficiently concentrate on the performance of their routine work.
Process Doer
Plans, executes, and improves business processes that deliver value to external customers, under the guidance of the process owner, and maintains the process capability and competence of the workers to deliver agreed plans of action and milestones.
Process Roles and Responsibilities in Succeed

QA Facilitator
Assures that processes reflect best practices and are compliant with external standards (ISO 13485, 9001, 14001, MDD, 21 CFR 820 etc.), including documentation and review according to the procedures established in the Succeed process.
Scope of the Current Succeed Implementation

✓ 1,500 procedures, work instructions, and templates
✓ 260 documented processes (increasing)
✓ 320 roles (decreasing)
✓ 450 changes annually
✓ 3,500 users (increasing)
Stages in Development of Succeed System Maturity

- **Awareness of process**
  - Chaotic

- **Repeatable process**
  - Reactive

- **Defined process**
  - Proactive

- **Managed process**
  - Effective

- **Optimised process**
  - Predictable

Performance:
- Ad hoc
- Alerts - Fire fighting
- Measured and monitored performance
- Early problem detection
- Scenarios used to simulate efficiency expansion projects

**System Maturity**
Collaborative Process for Developing Succeed

Procedures are developed into a relationship diagram and mapped into cross-functional end-to-end processes that deliver value to the external customers.

- Business Owner Approves
- QA Facilitates Process Mapping
- Process User Community Defines the Work Details
Snapshot of Succeed Information Technology

Management

- Develop Customer Solutions
  (Product & Process Realisation)
- Provide Customer Solutions
  (Operations & Supply)
- Manage Customer Needs
  (Sales & Marketing)

Supporting infrastructure
- Procurement
- Human Resources
- Corporate Communication
- IT
- Finance
- Medical Affairs
- EHS
- Legal
- Quality
- Regulatory

From customer needs to customer satisfaction
The Succeed IT system maps policy into processes which are broken down into procedures.

Succeed documents the end-to-end details of the Mölnlycke daily management system.
Structure of Succeed for Daily Management

Procedures are defined into detailed work instructions that are supported by forms and guidelines for implementation.
Current State of Succeed

- All functional areas have documented work processes and are supported by process teams.
- People are using Succeed in daily management; however, its implementation has not yet been consistently deployed.
- There is significant variance in maturity level between the daily management processes.
- There is some management uncertainty if the Succeed system will continue to meet the evolving regulatory and compliance requirements as the organization improves its performance to the next level.
Mölnlycke Health Care

Succeed in the Future!
Direction of global improvement

Enhance the Mölnlycke Health Care Quality and Compliance culture by creating the right capabilities and competencies which ensure customer insight so we act collaboratively with business acumen.

Short Term: Focus

• Focus Succeed on developing “right the first time” compliance in daily work processes, clarify and align cross-functional roles and responsibilities within the Succeed framework to manage process competence and capability.

Medium Term: Simplify

• Integrate regulatory rules and requirements into Succeed and streamline their impact on process work so that robust compliance may be assured across all requirements.
• Expand quality training and development to assure the consistent compliance and proactive improvement of the daily management system.

Long Term: Extend

• Mature this systemic, solution-oriented quality culture so that routine work of the organization achieves excellence and where the quality organization acts as a professional partner and customer advocate to the process owners and business leaders.
Areas for Future Evolution of Succeed

- The governance structure needs to be changed to support the shift in corporate governance and reporting systems.
- **Strategic** change of the Succeed system needs to be planned so that it integrates and supports the evolution of the Mölnlycke business strategy.
- The system needs to become more flexible to better support changes related to process improvements and to provide more robust support for shifting regulatory requirements.
- Increase the speed for cycles of learning to generate **continual improvement** and thus increase agility in the daily management system operations.
Get in Touch

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