ECA Academy
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GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Arnoud Herremans
Lean Kaizen Consultant,
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Dorthe Christina Kroun
Danish Medicines Agency, Denmark

Ann McGee
PharmaLex, Ireland

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KPIs and Quality Metrics

How to foster Continual Quality Improvement

Live Online Training on 18/19 February 2021

Highlights

- Quality Metrics
- Key Performance Indicators (KPIs)
- Continual Quality Improvement (CQI)
- Correlation with Process Controls, Quality Costs and Business Continuity
- Tools and Techniques
- Psychological Aspects

Objectives

This Live Online Training brings together well-experienced experts to discuss the latest expectations and requirements for Quality Metrics and KPIs and how they are linked to Continual Quality Improvement (CQI), the cost of non-conformance and Business Continuity. This will support you turning your company's quality excellence goals into reality.

Background

To remain 'regulatory compliant' and to ensure the continuity of product supply in a cost-effective way, systems and processes must be evaluated and the respective processes simplified and controlled. Important tools in this context are accurate Quality Metrics, the right Key Performance Indicators (KPIs) and Continual Quality Improvement.

Quality Metrics in itself are not new, though. They have already been used in pharmaceutical industry for years –mainly internally to measure operational performance. But quality can be measured on different levels and for many processes. Done in the right way, Quality Metrics can enable companies to reach a high quality performance. They will benefit from a continuous improvement in both operational performance and GMP compliance. And both are important for the continuity of business and product supply.

A good quality metrics system supports both industry's profitability and GMP compliance. But a good system precludes overproduction of metrics; you only measure what adds value to quality in the most efficient way. This way the metric system is fit for purpose, enables you to maintain a high quality standard and allows you to lower your costs for quality. This can drive the price down and renders continuity to the business at the same time. To make this happen, industry must come together in courses like this to learn and discuss how to build a better quality system using smart quality metrics.

Target Audience

Managers and Executives from pharmaceutical Quality Assurance and Quality Management but also Business Executives and Production Managers and those involved managing the continuity of product supply.

Moderator

Wolfgang Schmitt

Programme

Quality Metrics and beyond

- Expectations of the agencies
- Quality Culture as the basis for quality improvements
- How to involve the management in Quality Metrics
- Set up of a practical review system
- Follow up actions on management reviews

Integration of Quality Metrics Systems and KPIs in Continuous Improvement and Business Continuity

- Understanding critical processes & where quality risks lie/ process mapping
- Defining the right KPIs
- Meaningful metrics (and the pitfalls)
- The role of Quality Impact Assessment & effectiveness checks
- The link to Opportunities for Improvement (OFIs), Continuous Quality Improvements (CQIs) and Business Continuity

Psychological Aspects of Continuous Improvement

- What do the numbers tell us?
- Business culture
- Empowerment of people

Managing Data: The Bridge from Quality Metrics to CQI

- Defining the right KPIs and meaningful Metrics
- Insight to the St Gallen and Xavier University work
- What to learn from the data
- Example on vendor management

Quality Metrics Principles to foster Business Continuity

- Expectations of authorities, what is essential for performance metrics
- The link to ICH Q12: Quality Metrics as part of Product Lifecycle Management.
- Case Study: Continual risk mitigation to transform lagging performance data into leading Metrics and Quality Objectives

Assignment of Metrics and Correlation with Process Controls

- The importance of proper use and relevance of lagging and leading KPIs in correlation with process controls.
- The set up and implementation of a risk based data evaluation methods for continual improvement and the Management Review

KPIs and the Cost of Non-Conformance

- Quality by the numbers: what are quality costs?
- How to determine the cost of poor quality
- Quantify – analyse - improve
- Calculating return on investment

Constructing KPIs that drive high quality Behaviour - why many of our KPIs do the opposite

- Leading and lagging KPIs (what is the difference and how to use them)
- The effect of KPIs on behaviour: how KPIs can drive high quality behaviour

Case Study:

Quality Metrics as a Key Driver for CQI

- Why did we implement Metrics?
- How did we do it?
- What was the outcome?
- Lessons learned
- How to apply Quality Metrics as a Key Driver for CQI

Case Study: FDA's Quality Metrics Program

- Background
- What is the status of the FDA Quality Metrics Program?
- The new Quality Metrics Feedback Program and Quality Metrics Site Visit Program
- Case Study: Experience with the FDA Quality Metrics Pilot Phase

Wrap-up: What the Future will bring

- True understanding of the quality risks specific to our businesses
- A shift to pro-active QRM from reactive risk assessment
- Integration of QRM and change management
- Moving away from the functional silo mentality
- Process and QMS improvement in the interest of patient care
- Meaningful performance evaluation criteria and metrics

Speakers

Arnoud Herremans
Lean Kaizen Coach, Netherlands

Arnoud Herremans was Senior Scientist at Solvay Pharmaceuticals and Research Unit Manager at Abbott Healthcare. He has a psychological background (Behavioral Neuroscience at Utrecht University) and has been applying Lean - 6Sigma and Kaizen methods to the life sciences industry.

Henny Koch
Qimp Management Systems B.V., Netherlands

Henny Koch is Managing Director at Qimp Management Systems B.V. During 36 years in pharmaceutical industry he held several positions in R&D, Manufacturing and Quality. Since 2012, he is active as quality consultant within Life Science Industry.

Dorthe Christina Kroun
Danish Medicines Agency, Denmark

Dorthe Kroun is an Inspector at the Danish Medicines Agency DKMA. She has experience as Senior Quality Manager and Site QA Head and held various QA positions.

Ann McGee
PharmaLex Ireland, form. Senior Inspector of the Irish Medicines Board

Ann McGee is Managing Director PharmaLex Ireland and has extensive experience both in the pharmaceutical industry and as a regulator. She is a former Senior Inspector of the Irish Medicines Board, Chief Executive of the Pharmaceutical Society of Ireland and Deputy Chair of PIC/S.

Jason McGuire
Fagron, USA

Jason McGuire is Vice President and Global Quality Director. He has been working many years in pharmaceutical and healthcare industry, from QA/QC to Business Development and Operational Excellence.

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Reservation Form (Please complete in full)

KPIs and Quality Metrics
Live Online Training on 18/19 February 2021

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

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E-Mail (Please fill in)

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Date of the Live Online Training

Thursday, 18 February 2021, 9.00h – 17.00h
Friday, 19 February 2021, 8.30h – 16.00h
All times mentioned are CET.

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference Language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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