ISPE COP PAT & LCS “PAT & LIFECYCLE CONTROL STRATEGY”
“PRODUCTION CONTROL STRATEGY IMPLEMENTATION”

OPERATIONS EXCELLENCE
IN COMMERCIAL MANUFACTURING
ENGINEERING & AUTOMATION

Workgroup “Production Control Strategy”
1st WebMeeting, ISPE D-A-CH CoP “PAT & LCS”

WebMeeting
11.7.2016

Christian Woelbeling

Member of the ISPE:
- Global Steering Team Member CoP „PAT & LCS“
- KNC Council Secretary
- PDPS Council Member
- DACH Affiliate Member

c/o Werum IT Solutions GmbH
Agenda

1. Summary & Status of the Production Control Strategy Project
2. Scoping of the Production Control Strategy – Key Topics – Brainstorming
3. Defining Sub teams
4. Initial F2F Meeting
   1. Fixing a date 1-2 days?! Week 41 / 42
   2. Sponsor for the meeting
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Proposed Projects

Focus Production Control Strategy Implementation

1. “Production Control Strategy Implementation Awareness Document”
   - Status today and the gaps
   - Roadmap for future implementation and the impact on Data Integrity
   - As e.g. ISPE Pharmaceutical Engineering Article

2. IT Automation System Structure & Integration Standardization
   - Blueprint for a “Best Practice” based system architecture implementation (S95 Level 2 to Level 3)
   - As e.g. ISPE Guidance Document

3. “QbD” Workflow Execution – The Process Control Strategy
   - Methods for the MVDA based Process Control Strategy (Basis e.g. aMab Study Page 90 - from description to feedback control) incl. a predictive process control
   - As e.g. Extend the ISPE “aMab Study” by the Process Control Strategy Implementation
1. Production Control Strategy Implementation

**Awareness Document**

**Content:**
- Status today and the gaps
- Summarize the content, impact & goals of the ICH Q8 to 12 in regard to the Process Control Strategy
- Roadmap for future implementation (e.g. System Blueprints)
- Impact on Data Integrity

**Goals:**
- Explain the importance of the Control Strategy in the FDA paradigm to the industry
- Explain the Importance of the collaboration of QA, Engineering, Manufacturing etc. for implementing the Production Control Strategy
- Create awareness on management level
Control Strategy Terminology

- **Master Production Control Record** (Refer also to new FDA DI Draft Guidance)
  - GMP 21CFR 211.186

- **Submission Control Strategy** (Process Development)
  - ICH Q8 (R2) – Pharmaceutical Development
  - ICH Q10 Pharmaceutical Quality System
  - Drug substance / product focus
  - CQA & CPP & CMA per submission

- **Production Control Strategy** (Commercial GMP Manufacturing)
  - Plus GMP controls
    - Environmental controls
    - Equipment & Facilities controls
    - Automation Control Strategy
    - Material Controls
  - Environmental, Health, and Safety / EHS controls
Status

Current Status in the Global ISPE Community

- March 2016:
  - “Production Control Strategy Implementation” Project proposed to the ISPE Board

- June 2016
  - Project proposal Accepted & Next Steps
    - Presentation at Facilities of the Future Event (Nov 16)
    - Articles for the “Pharmaceutical Engineering Magazine” (in 2017)

- Potential extension of PQLI to be decided (in 2017)
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Understanding the Scope of the Production Control Strategy

Knowledge Management
Regulatory Doc Management

Quality & Compliance
Data Integrity
Data Analysis
Predictive Analytics & Control
CPV

Production Control Strategy
Manufacturing Process
Work Instructions / MBR / EBR / MPCR

Integration
ALCOA+ Operator & Equipment manual / automatic data capture via HMI, PLC, DCS, SCADA

Regulatory
APR/PQR
Process Quality Performance

Performance
Data Analysis
OEE/KPI
## Production Control Strategy Implementation Project Table of Content

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1. Idee: Mit einer ISPE Veranstaltung/Anschluß
Your Impression / Feedback / Ideas ?!?!

Thank you for your attention.

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