Trends in Pharmaceutical Quality Assurance
Perspectives of the Industry and Academia

Alesandro Marangon, Ph.D., MBA
Disclaimer

The content presented herein reflects solely author’s unbiased opinion with no connection or influence from any employer or pharmaceutical company.
Introduction

Background
- Born in Brazil
- Italian Family
- Educated in Germany

Education
- Grad. in Pharmacy
- PhD in Pharmaceutics – University of Tuebingen
- MBA International Management – Berlin and Cambridge (UK)

Professional Experience
- Project Management R&D pre-clinical and clinical
- Manufacturing of clinical supplies
- Quality Assurance
- Procurement and Sourcing
Quality Assurance in Pharma

*Quality Assurance is present in overall pharmaceutical value chain*

**Typical activities**
- Pre-clinical research
- Clinical research
- Formulation development
- Tech transfer
- Commercial production
- Quality Control
- Distribution
- Warehousing
- Post-marketing surveillance
- Management of product incidents

**Typical QA function**
- Management of GLP
- Release of clinical samples
- Management of GCP during clinical studies
- QA GMP compliance
- Auditing
- Batch release
- Management of GDP activities
- Management of product incidents

GLP: Good Laboratory Practices
GCP: Good Clinical Practices
GDP: Good Distribution Practices
Why Quality Assurance is important?

- Increasing number of QA related FDA Warning Letters
- Data integrity issues more than tripled in 2011 to 1720

Source:
PwC Health Research Inst. FDA WL.
Why Quality Assurance is important?

*Consent decree is a drastic consequence of poor quality management*

- If a firm has repeatedly violated cGMP requirements, the FDA may make a legal agreement with the firm to force them to make specific changes; the agreement, the consent decree, is enforced by the federal courts.

- A typical consent decree can last 3-5 years and cost USD 500M
  - Fines and penalties
  - Lost sales
  - Remediation costs
  - Impact on reputation
Key Industry Trends

1. Outsourcing and virtual manufacturer
2. Shift to personalized therapies
3. Blockchain and drug traceability
4. Artificial Intelligence and drug safety
5. Wearable devices and mHealth
Virtual Manufacturer

*Flexible business model relies on the management of the supplier footprint*

- Pharma company as IP owner and operations outsourced
- Flexible business model with cost benefits
- Challenge control of supplier footprint

Source:
Shift to personalized therapies
Paradigm shift from one-size-fits-all to precision medicine

Source: Frost & Sullivan - Figure 1: New Paradigm Shift in Treatment
DNA sequencing drastic cost reduction

*Reduction of costs enabling personalized treatment*

The rise of personalised medicine is supported by a rapid decline in the costs of genome sequencing.

Cost of sequencing human genome 2001-14

- The rate of progress in genome sequencing has outpaced Moore’s law since 2008
- Moore’s law

Source: National Human Genome Research Institute
The Rise of Blockchain

The impact of drug counterfeit

- Drug counterfeits accounts with 1M deaths annually

Source: PWC. Fighting counterfeit pharmaceuticals: New defenses for an underestimated. 2017
The Rise of Blockchain

*Blockchain to improve drug traceability*
Artificial Intelligence and Drug Safety

*Al to enable monitoring of adverse reactions*

- Engagement model with patients shifting to social media
- Real time monitoring of adverse reactions

Source: Digital Pharma News. Oct 2018
Monitoring technologies

Wearables and mHealth growing exponentially

- mHEalth market grew 10x from 2013 to 2017 and still less than 1% of total market

Transformation of Healthcare Models

Beyond the pills

Supply drivers

Medical & patient data
Electronic health records (EHRs), health sensors, social media, and genomics create rich new data sources for analytics.

Big Data analytics
Cheap computing power and sophisticated analytics drive insights into patient behaviour, treatment costs and R&D.

Mobile/mHealth
Pervasive mobile and smartphone adoption creates new engagement models within daily routines.

Healthcare professional digital workflow
Increasing integration of EHRs and telehealth driving new digitally-enabled coordinated workforce models of care.

Demand drivers

Rollout business models tied to patient outcomes that also reduce medical errors and improve quality.

Discover and deliver targeted and personalised therapies with real world evidence of impact.

Influence patients’ behaviours "beyond the pill" and sustain engagement outside the traditional care setting.

Drive population management, protocol driven patient risk pool and stratification management.
Key QA Challenges with New Technologies

How Quality Assurance practices will evolve with the current trends?

• **Personalized therapies**
  – Lack of standardization
  – Early stage: e.g. CAR-T now as Biotech 20 years ago
  – Regulatory framework evolving
  – Shift from traditional manufacturing to cell processing centers

• **Artificial intelligence, Big Data and Blockchain**
  – Cybersecurity
  – Data confidentiality and security
  – Difficult acceptance in the medical community
Perspectives of the Academic World

Are current educational programs adapted to QA careers and trends?
Quality Assurance skills set

- Analytical skills
- Organizational skills
- Excellent written communication
- Interpersonal skills
- Keen attention to detail
- Critical/logical thinking
Missing the link: Competency-based learning is not a reality yet

Lack of alignment between higher education programs and current needs of Pharmaceutical Global Markets

<table>
<thead>
<tr>
<th></th>
<th>Traditional Education</th>
<th>21st Century Education</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criterion for Curriculum Organization</strong></td>
<td>• Disciplinary content to be covered during the course or program</td>
<td>• Competencies to be developed as outcomes of the course or program</td>
</tr>
<tr>
<td><strong>Teaching</strong></td>
<td>• Coverage of prescribed disciplinary content • Lecturing</td>
<td>• Uncovering relevant and personalized meanings • Facilitating</td>
</tr>
<tr>
<td><strong>Learning</strong></td>
<td>• Cognitivism • Consumption and processing of disciplinary content</td>
<td>• Constructivism • Task-oriented learning: problem-based learning, project-based learning, internships</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
<td>• Assessments of disciplinary content processing • Focus on summative assessments (assessment of learning)</td>
<td>• Assessment of applied learning &amp; skills development • Ample formative assessments (assessment for learning)</td>
</tr>
</tbody>
</table>

Source: . Competency Based Curriculum as a Means for Linking the Outcomes of Higher Education and the Job Market Needs Presentation of Dr, Suad Alazam
You are hired as Quality Assurance Manager for Pharma Co. There is a building dedicated for the productions of solids dosage forms as tablets in the company where the QA team is located. This week the company is running a batch of a film-coated tablet used as analgesic, however the batch did not pass the dissolution test in the Quality Control. The results are out of specifications. The commercial team calls you in order to understand if the batch can be released.

What would you do in this situation?
Key Takeaways and Discussion

• Paradigm shift of Healthcare models
• High level of digitalization
• Genomics playing a relevant role in personalized therapies
• Manufacturing models – cell processing
Thanks

Visit my website for further online lectures:
www.scientistexecutive.com