Trends in Pharmaceutical Quality Assurance Perspectives of the Industry and Academia

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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

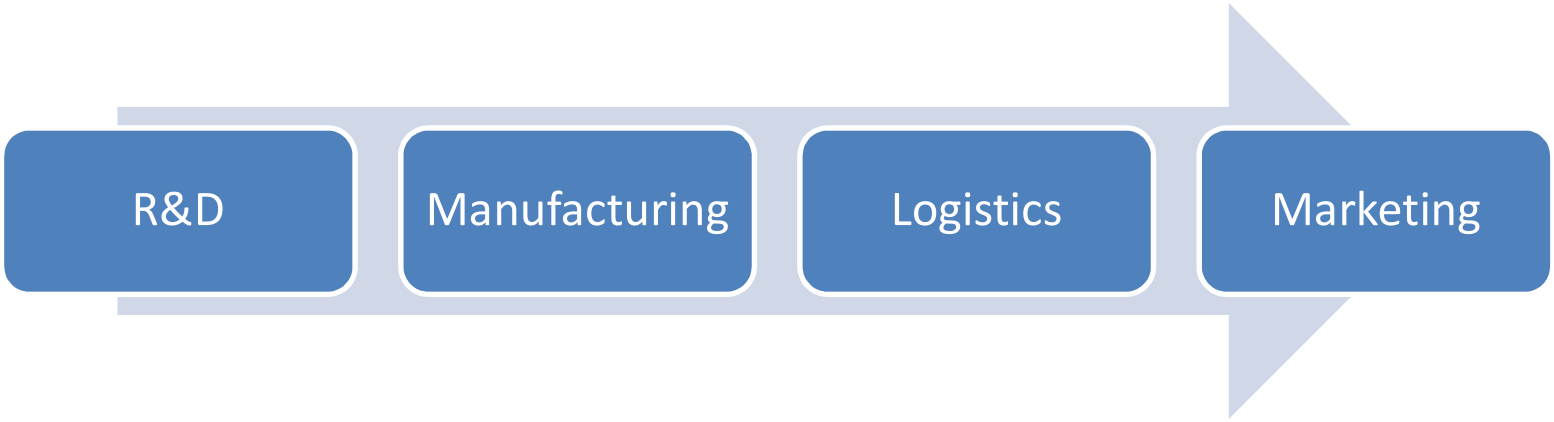
- Grad. in Pharmacy
- PhD in Pharmaceutics – University of Tuebingen
- MBA International Management – Berlin and Cambridge (UK)

Professional Experience

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

Quality Assurance in Pharma

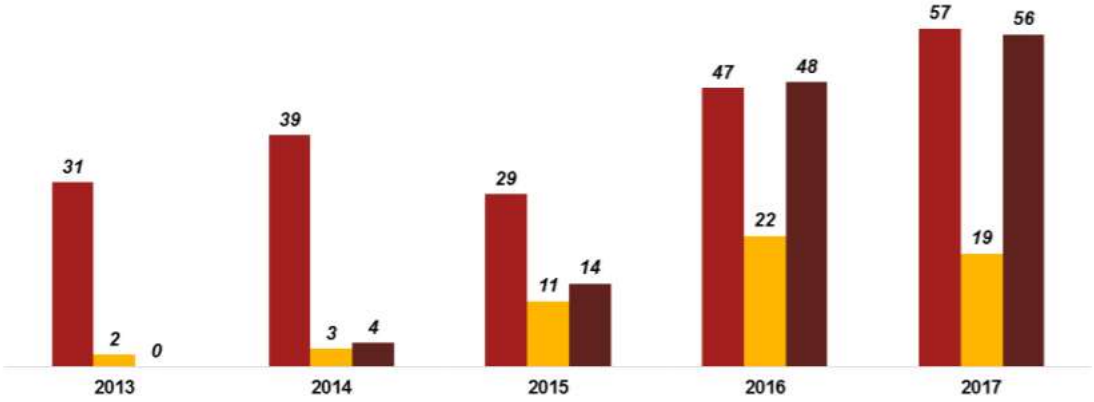
Quality Assurance is present in overall pharmaceutical value chain



	R&D	Manufacturing	Logistics	Marketing
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

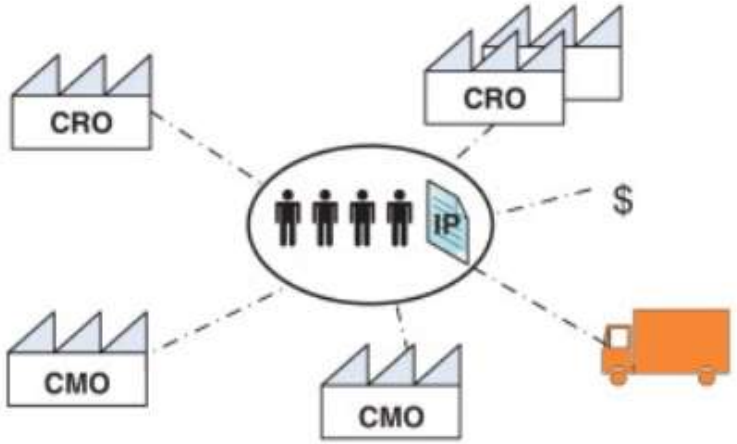
- A typical consent decree can last 3-5 years and cost USD 500M
  - Fines and penalties
  - Lost sales
  - Remediation costs
  - Impact on reputation

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

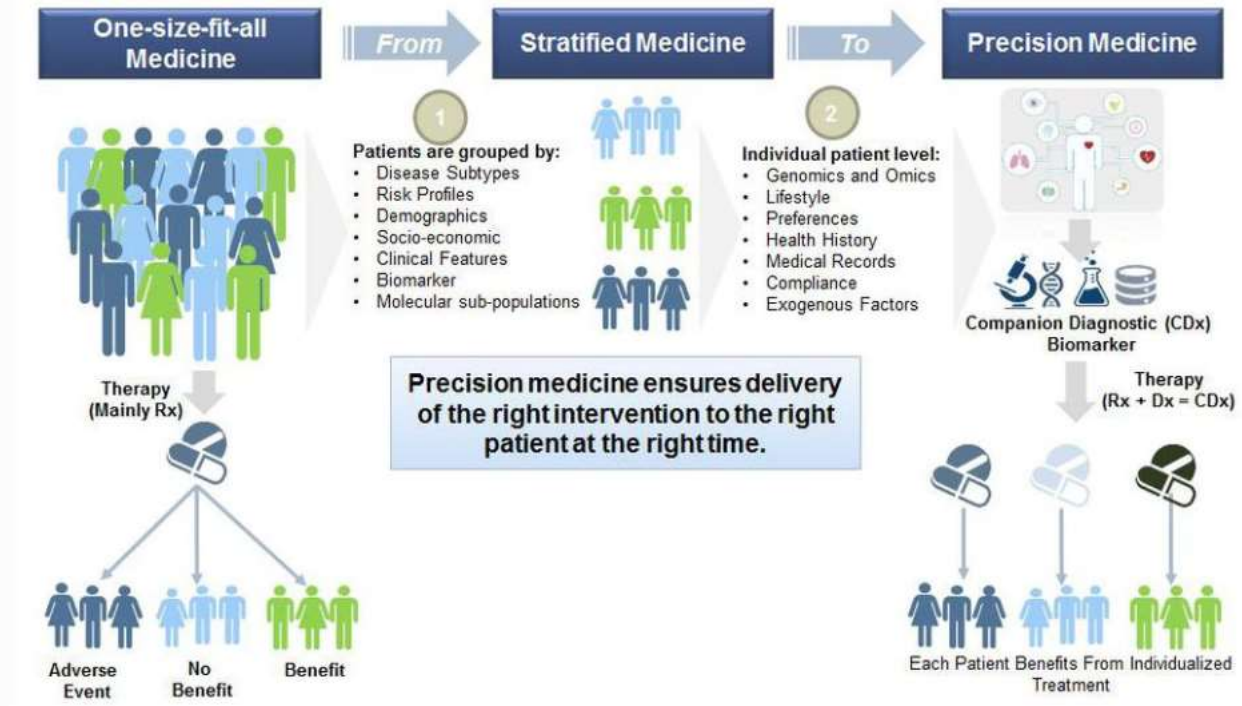


- Pharma company as IP owner and operations outsourced
- Flexible business model with cost benefits
- Challenge control of supplier footprint

Source:
Geri Studebaker. Managing CMO Networks. Contract Pharma, 2011

Shift to personalized therapies

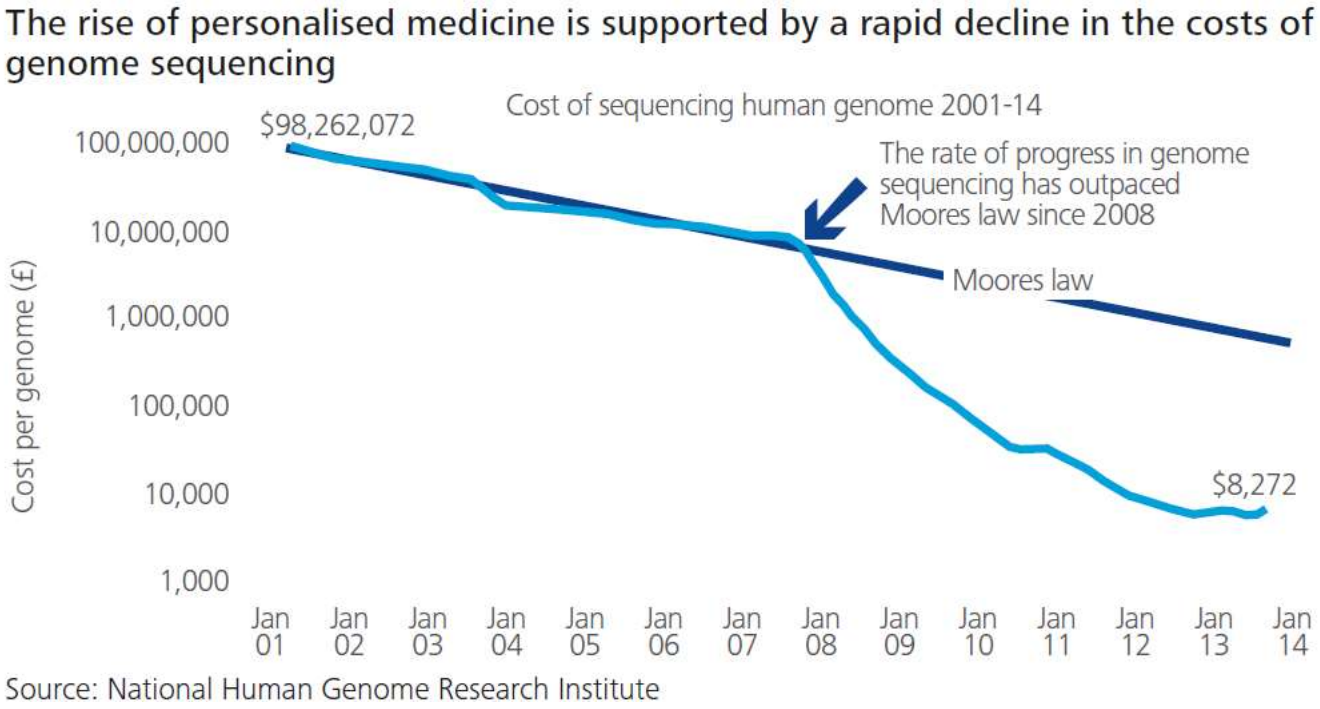
Paradigm shift from one-size-fits-all to precision medicine



Source: Frost & Sullivan -Figure 1: New Paradigm Shift in Treatment

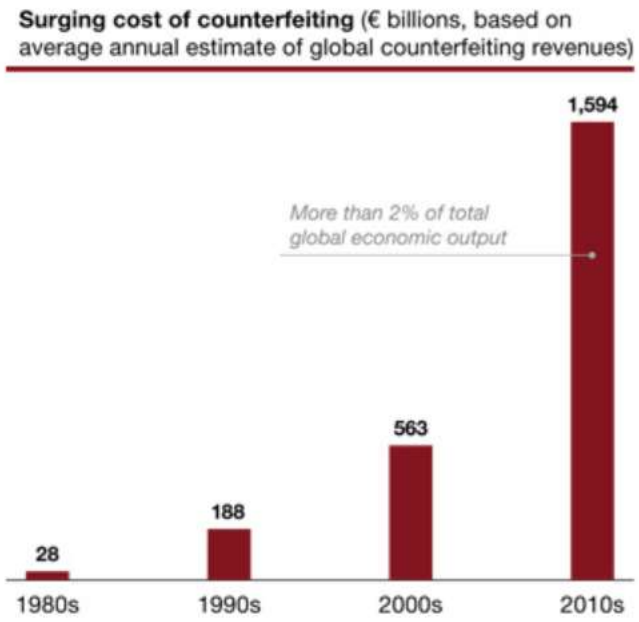
DNA sequencing drastic cost reduction

Reduction of costs enabling personalized treatment



The Rise of Blockchain

The impact of drug counterfeit



Global counterfeiting market by sector (€ billions)
2013 estimates, not all sectors included

Prescription drugs	188
Electronics	158
Foods	46
Auto parts	42
Toys	32
Clothing and shoes	23
Sporting goods	6
Tobacco	4
Cosmetics	3
Aircraft parts	2
Weapons	2
Alcohol	0.9
Watches	0.9
Diplomas and degrees	0.9
Pesticides	0.7
Money, IDs, and passports	0.3

- Drug counterfeits accounts with 1M deaths annually

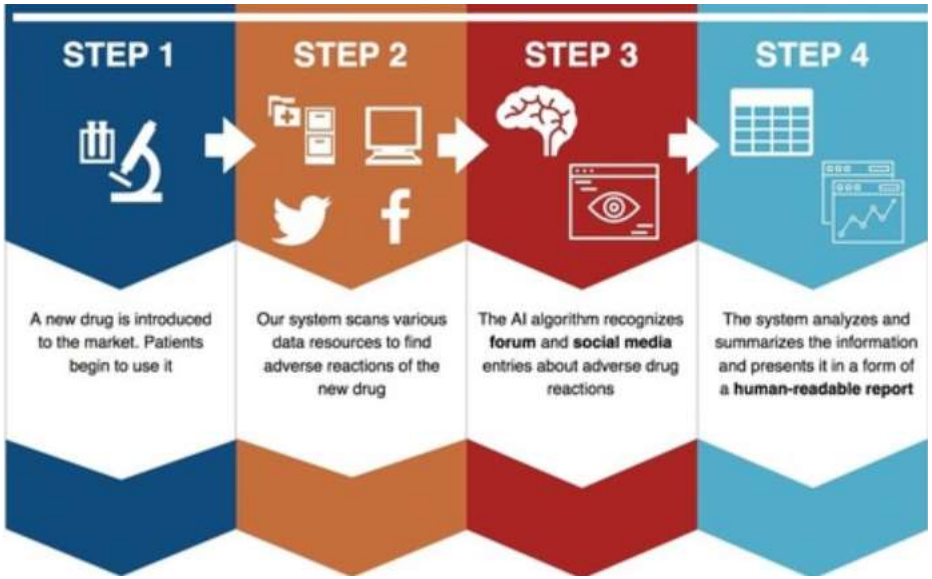
Source: PWC. Fighting counterfeit pharmaceuticals: New defenses for an underestimated. 2017

The Rise of Blockchain

Blockchain to improve drug traceability

Artificial Intelligence and Drug Safety

AI to enable monitoring of adverse reactions

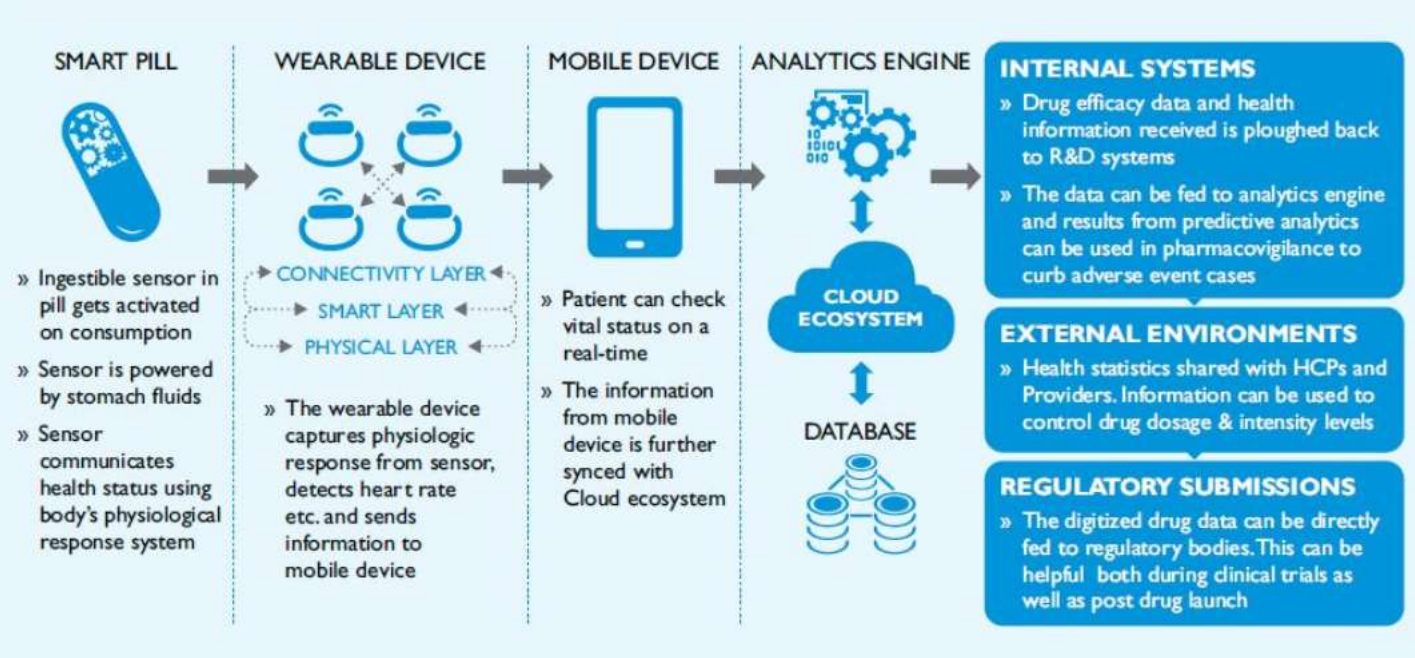


- Engagement model with patients shifting to social media
- Real time monitoring of adverse reactions

Source: Digital Pharma News. Oct 2018

Monitoring technologies

Wearables and mHealth growing exponentially

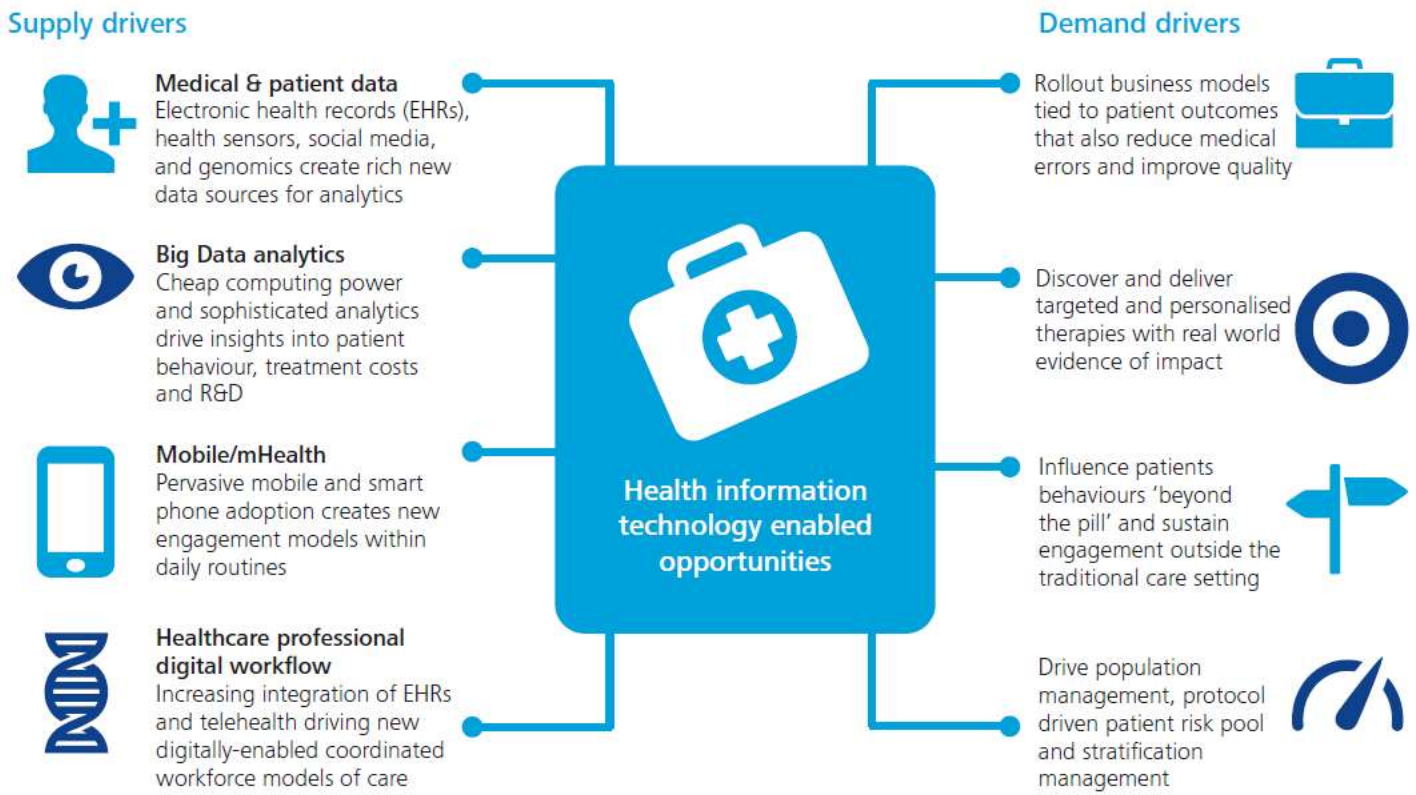


- mHEalth market grew 10x from 2013 to 2017 and still less than 1% of total market

Source: Deloitte. Healthcare and Life Science predictions 2020.

Transformation of Healthcare Models

Beyond the pills



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

Issue

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

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

Source: . Competency Based Curriculum as a Means for Linking the Outcomes of Higher Education and the Job Market Needs Presentation of Dr, Suad Allazam

Issues with the Batch Release

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

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