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Pharmacists Education in Germany and Educational Needs of Pharmacists in the Pharmaceutical Industry

FIP - September 2008

Dr. Thomas Schneppe

BHC PS C IQM Mgmt. Training

Dr. Thomas Schneppe

1984-1989	Community Pharmacies
1989-1992	Klöckner Pentapack (Contract Manufacturer) - Head of QC/QA - Qualified Person AMG
1992-2006	Schering AG - QM System Schering AG - Audit + Authority Inspections - Compliance + Reorganization Projects - Internal GMP Consultancy for Functions + Sites - Head of Compliance Management Training Function
since 2006	Bayer Schering Pharma AG - Head of Integrated Quality Management Training

Pharmaceutical Education in Overview

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Harmonization based on EC Directive 2005/36/EC

Approbation

- 4 years at university (minimum); extended within european harmonization from 3.5 years (clinical pharmacy added)
- 1 year on job: Community pharmacy (min. 6 months), hospital, industry…

Continous Education

- Seminars, publications…; certificates at a certain level / 3years

Optionally + Diploma + Thesis

- Additionally the possibility to get a Diploma (proof of capability to work scientifically) is offered by some german universities

Optionally + Post Graduate Specialization

- Types depend on regional specifics

12 month of Experience …

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To be covered within the 12 month…

Recepture, Defecture, Manufacturing Processes for Drug Products

Development, Application and Manufacture of Drug Products

Planning, Disposition, Storage, Stability

Information/Communication on effects, side effects, incomapatibilities, mis-/abuse…

Quality Control and Quality Assurance

Self Medication

Hygiene, Nutrition, Crop Protection, Diagnostics, Services…

Economics, Laws, Institutions…

… and to be examinated, e.g.

… Quality Assurance for Manufacturing and Testing of Drug Products incl. Statistical Methods; legal foundation of Quality Assurance, , Validation, IPC and Final Testing, Stability + Stabilizing Incompatibilities and Interaction…

Post Graduate Specialization

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Frame + general content defined by federal pharmacist association

Locations and trainers to be approved by regional chambers

120 seminar hours within 3 years

„Expert Pharmacist for…“

- Community Pharmacy
- Clinical Pharmacy
- Drug Product Information
- Pharmaceutical Technology
- Pharmaceutical Analytics
- Toxicology and Ecology
- Theoretical + Practical Education
- Public Health Affairs
- Clinical Chemisty

Additionally and sometimes only regionally offered: Nutrition, Health Consulting, Oncology, Natural Therapies + Homeopathie, Geriatry, Home Care, Education.

Pharmaceutical Education – The future?

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Bachelor and Master – still under Discussion in Germany

- Bachelor (3-3,5 years university)
- Master (Bachelor + additional 1,5-2 years)

Position Paper AK Galenik, 2004
7 Pharmaceutical Companies
Members personnel view

- For Master improved Opportunities in Pharmaceutical Industry expected, for Bachelor fewer Opportunities expected
- Internationalization of Education within EC appreciated (languages)
- Education should focus more on qualification for „qualified person(s)“
- Thesis will remain an important qualification factor for Pharm. Industry
- Thesis should not exceed 3 years

„The Pharmacist“

„Das Berufsbild des Apothekers“,
ABDA 2004, ISBN 3-7741-1024-7

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ABDA/WIV – Pharmacists 2007:
47.766 in community pharmacies
1.762 in hospitals
7.191 in all other are inc. Industry
„More specific data are not available“

Based on „Code of Ethics“, 1997 FIP and Resolution ResAP 2001, EC

Main Fields of Activity

Public Pharmacy
Hospital
Pharmaceutical Industry
Test Institutes
Army
Authorities and Public Bodies
Universities and Schools

Main Tasks and Responsibilities

Information
Manufacturing
Quality Assurance
Quality Control
Storage and Distribution
Risk Assessment
Research and Development

The Pharmacist in Pharmaceutical Industry

Qualified Person acc. to EC GMP regs.
Quality Mgmt., Quality Assurance, TQM
Manufacturing and Quality Control
GMP Compliance and Validation
Transfer from Development to Routine
Training
Info/Dokumentation of Risks/Side Effects/Mis-use/Defects/Interaction, Pharmacovigilance…
Research and Development
Mgmt. of Clinical Trials
Drug Regulatory Affairs
Marketing and Distribution
Public Health Politics

Fit / Gap?

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Provide skills for Learning on the job

Approbationsordnung 1993 Total of hours: 3104	% of hours	Pharmacists at Bayer PH 2002: Rough %	Pharmacists at Bayer Schering Pharma 2008: %
API Chemisty, Excipients	14,9%		
Pharm. Analytics	12,6%	6% Pharm. Analytics (Dvpmt.)	3,4% Pharm. Analytics (Dvpmt.)
Basics, Mathematics…	9,0%		
Biology, Human Biology	12,6%		
Bio-/Pathobiochemisty	6,3%		
Technology, Biopharmacy	6,3%	13% Technology (Dvpmt.)	14,6% Technology (Dvpmt.)
Biogenic API	7,7%		
Med. Chemisty + API Analyt.	13,5%		
Pharmacology + Clin. Pharmacy	13,2%	7% Pharmacology	13,5% Pharmacology
Area of Choice; Special Interest	3,9%		
		25% QC + QA/QM	6,2% QC + QA/QM (HQ, shift to sites)
		21% Production Drug Product	16,2 % Production Drug Prod. SC
		13% Registration	15,2% Registration incl. CMC
		8% Info Mgmt.	
		7% Marketing + Distribution	
			9,6% Administration + Procuremtent
			16,2 % Project-/Study Mgmt. Dvpmt.
			5,1% Med..Affair./Pharmacovigilance

Conclusion:
The Majority of Pharmaceutical Activities in the Pharmaceutical Industry is not directly linkeable to the actual Education Profile.

The Industry Pharmacist

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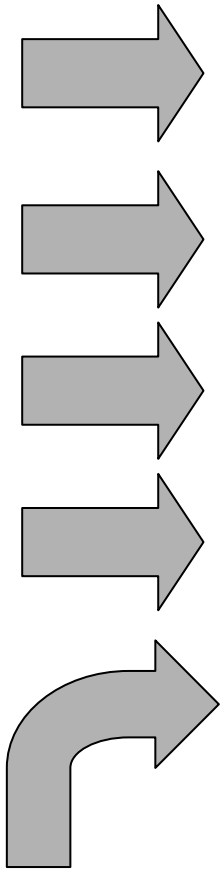
Pharmacists at BSP 2008

3,4%	Pharm. Analytics (Dvpt.)
14,6%	Technology (Dvpt.)
13,5%	Pharmacology
6,2%	QM/QA + QC (divisional)
16,2%	Production (Supply Center)
15,2%	Registration + CMC
9,6%	Administration + Procurement
5,1%	Med. Aff. + Pharmacovigilance
16,2%	Developmt. Project-/Study Mgmt.



Industry Pharmacists typical tasks:

Pharm. Development, ICH Q8
Quality Risk Management, ICH Q9 — Example
Quality Mgmt. +System , ICH Q10 — Example
Qualification and Validation — Example
Production and Projects
Legal Roles, e.g. Qualified Person — Example
Operative QA and Quality Control
Change Management
Pharmacovigilance
Project-/Study Mgmt. In R+D — Example
Auditing, QAAs, Supplier Mgmt. — Example
…

6-12 month public pharmacy foster customer orientation and communication skills.

Pharmaceutical education fosters a broader view and interface understanding.

WIV: Tendency from Expert (e.g. Analyst) to Generalist (e.g. Project Mgmt., QA/QM).

Complexity: GMP Rules and State of Art

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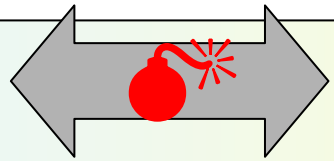
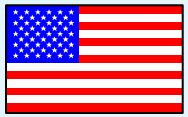
Legally binding



State of the Art

21 Code of Federal Regs.
- Part 11 IT Security
- Part 210/211 GMP
- …

Pharmacopeia (USP)



Guides to Inspection
Guidance for Industry

EC Regulations
EC Directives

EC GMP Guide
Pharmacopeia (EP)

Aide Memoires

Complexity: Tasks of Qualified Persons

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Qualified Person(s)

EC 2001/83 Art 48-51 + Annex 16 EC

Individual responsibility, delegations possible to other QP(s) only

- Certification (Compliance with GMP rules and Marketing Authorization)
- Register of batches produced/imported

Complaint System and Recall System
EC Guide Chap.8
+ 75/319/EC Art. 28
QP or other person,
QP to be informed…

Head of Production

Delegations possible

- Production/Storage acc. to SOPs
- Approval of Production SOPs
- Evaluation of Batch Records
- Check maintenance of premises
- Ensure appropriate validations
- Ensure adequate training

QP to ensure

Head of Quality Control

Delegations possible

- Approval/Rejection of materials/products
- Evaluation of batch records
- Ensure all necessary testing
- Approval of specifications, test methods, sampling instructions, QC-SOPs
- Approval/monitoring of contract labs
- check maintenance of premises
- Ensure appropriate validations
- Ensure adequate training
- Additional duties acc. to chapter 6

Joint tasks (depending on national regulations)

- Monitoring and control of environment, plant hygiene, storage conditions, general GMP
- Process validation
- Training
- Approval/monitoring of suppliers and contract manufacturers
- Sampling, retention of records

EC GMP Guide

The GMP Challenge

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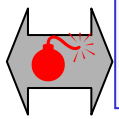
„…Six-sigma products on the market with three-sigma processes…“

Gerry Migliaccio, VP Global Quality Pfizer

Bridging the gap:

- Risk Assessments
- Qualification and Validation
- Monitoring, PQR, CAPA
- Rework, Reprocessing
- Deviation/Complaint Mgmt.
- Self inspection
- ...

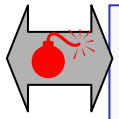


Comment from QPs…

Detailed QC knowledge is expected by §13 AMG but focus should be more on QA: CAPA, PQR, OOS…

Comments from QPs…

EC shall expect 2 years experience in QA, Reg. Aff., Production and QC instead to focus so much on QC.



Comments from QPs…

Acc. to EC regs. only the QP usually is a Pharmacist; Heads of QC or Production may not be pharmacists.

„Knowledge of the Qualified Person must exceed that of Leonardo da Vinci, Albert Einstein, and Jesus Christ“ Garry Prout, Valent Pharmaceutical, RPS UK 2005

Complexity: Launch Mgmt.

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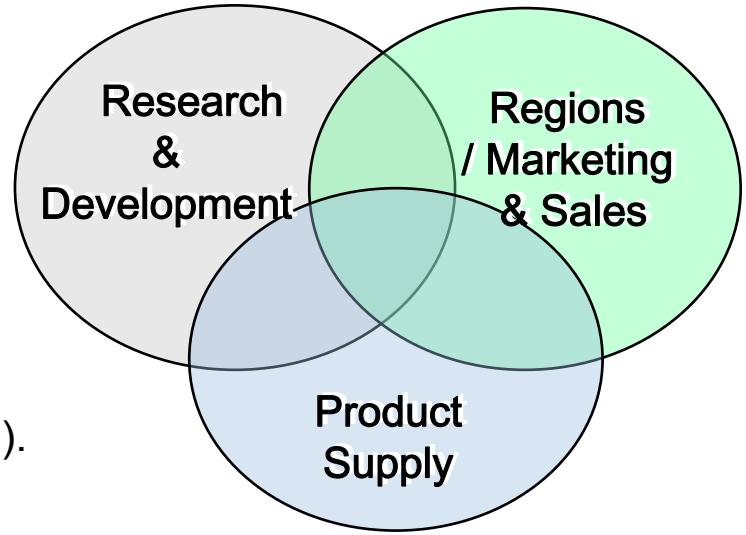

- Product related prime contact and interface to internal partners (R&D, BU/Marketing, Regions) and within Product Supply (Production, QA etc.).

- Following the R&D operating model asking for a single representative of affected functions in the Global Project Team (GPT)

  ⬇

  The OM / LPM is the Representative of Product Supply in the Global Project Team (GPT), CMC Development Team (CDT) and Global Brand Team (GBT)

- Project management within Product Supply to channel information to project teams and management, and to coordinate the preparation for the product launch

Complexity: ICH Q 10 Quality Systems

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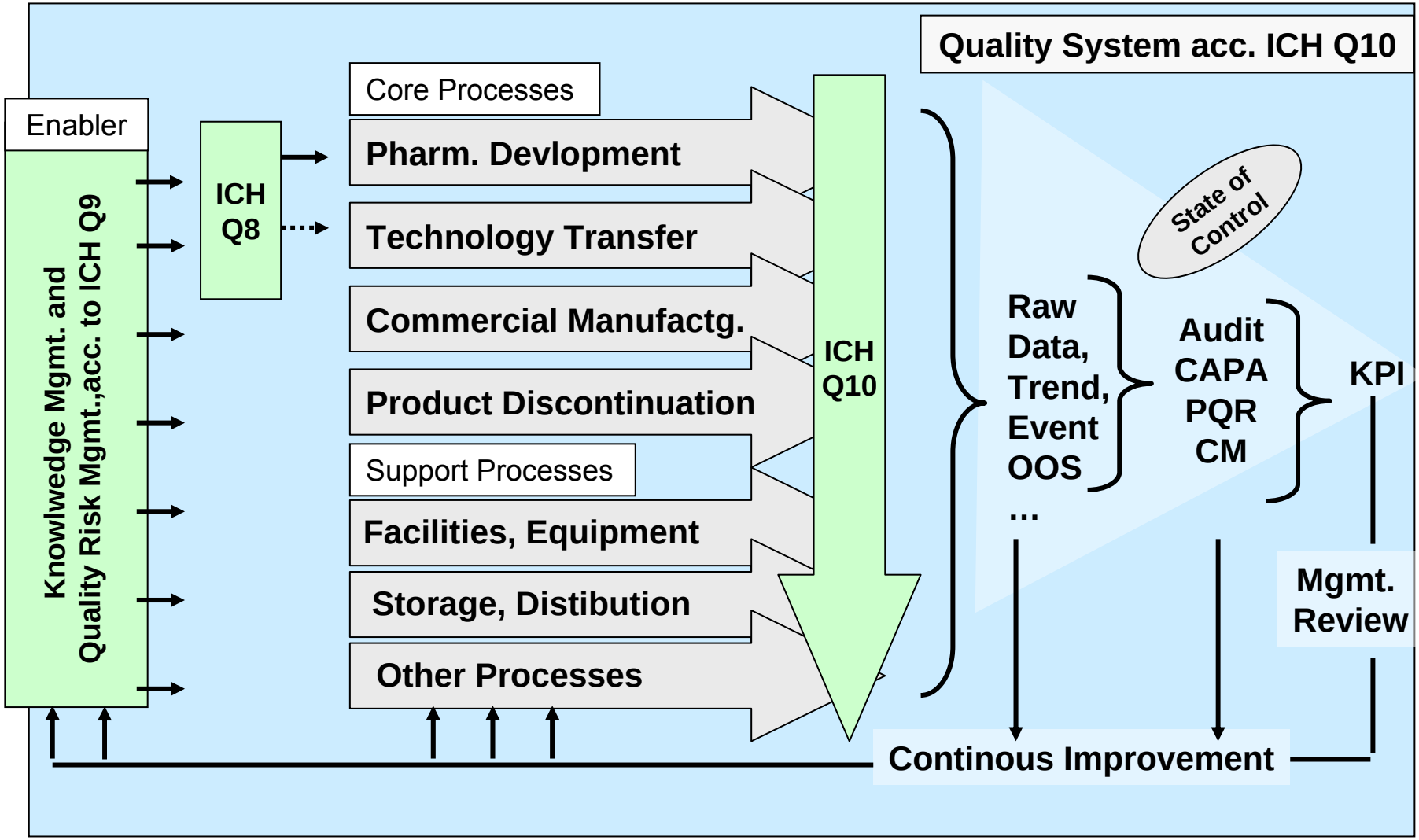
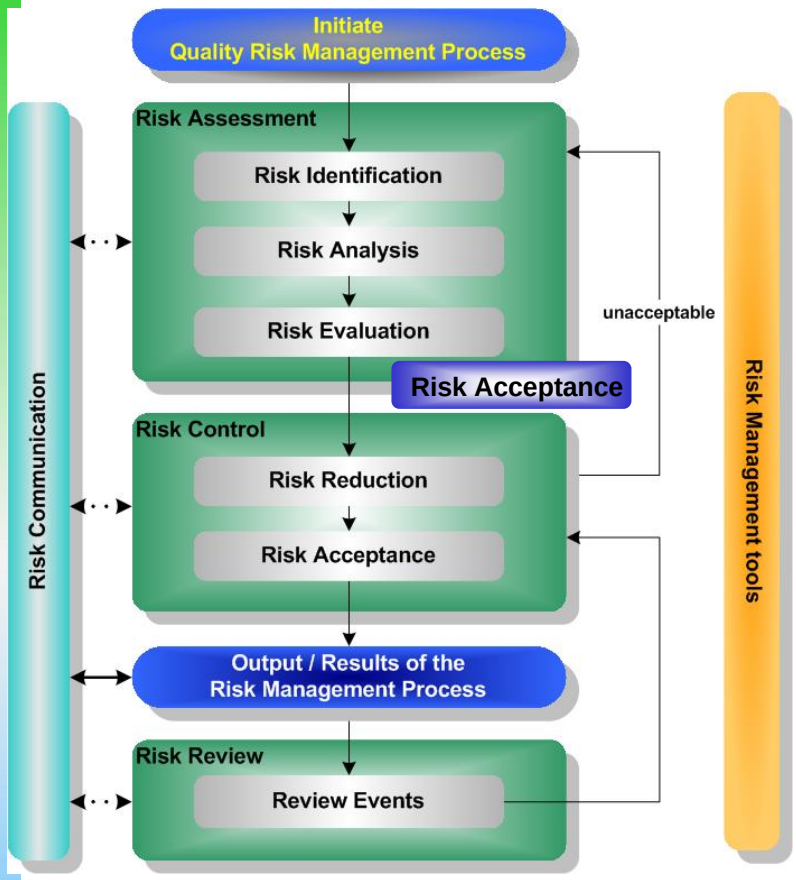


Knowledg Mgmt.:C hange Control, SOPs + Specs., Development Report, Techtransfer, Validation Plan + VMP, PQR, CAPA…

Complexity: Quality Risk Mgmt. Acc. to ICH Q9



	identification	analysis / evaluation	reduction / mitigation	acceptance	reporting	review
Informal	X	(X)	(X)	X	X	(X)
Ishikawa	X	-	-	-	(X)	-
FTA	X	-	-	-	(X)	-
FMEA	X	X	X	(X)	X	-
HACCP	-	-	X	(X)	X	X
HAZOP	-	-	X	(X)	X	X
SPC	-	-	-	-	X	X

Complexity: Qualification and Validation

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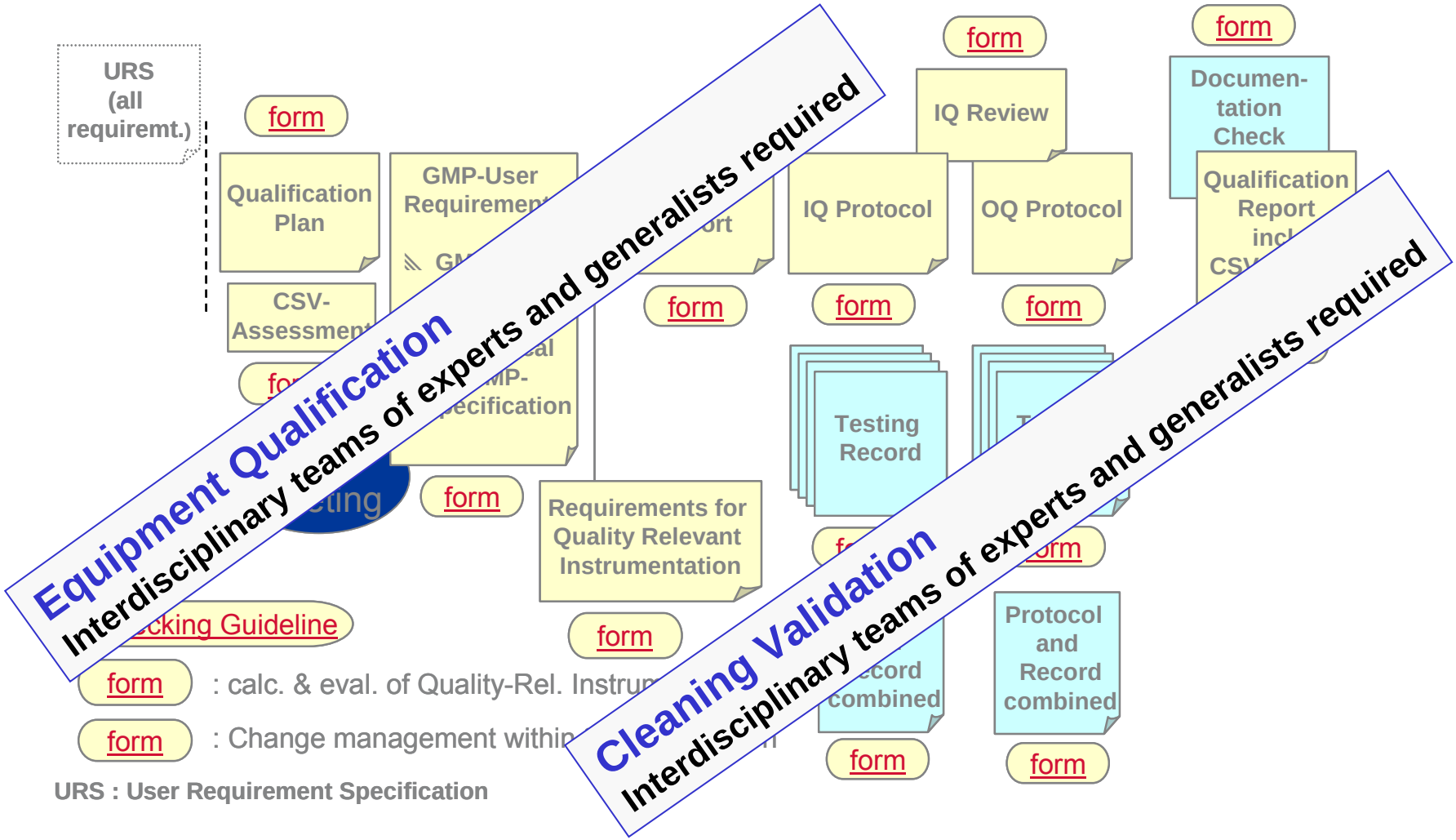

Complexity: Audit and Inspection

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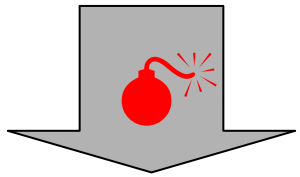
Pharmacists domaine:
processes in overview
interfacing/networking
customer orientation
communication skills
internal consulting
insp. preparation
mock inspection
auditing

Example: FDAs 6 Systems
1. Quality System
2. Facilities/Equipment System
3. Materials System
4. Production System
5. Packaging + Labeling System
6. Laboratory Control System

2-6 systems/inspection



FDA: „If any system Is out of control, the firm is out of control“

 # Form 483 + Home Report
 # Warning Letter
 # Concent Decree
Debarment list
Product recall/seizures
Manufacturing Restrictions
Submission delayed/withdrawn

My Conclusions

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„Fit for Future“…
From operative and QC
to QA, Systems/Processes

- Many established fields of activity exist and remain, e.g. Production, Q, Reg. Aff., R&D….
- Fostering of process orientation leads to further options
- Pharmaceutical education can be optimized in fostering QA/QM/Compliance skills.
- Additional skills (e.g. languages) can be very supportive for employment in Pharm. Industry.
- Pharmacists have a unique profile: Generalists, team, customer and „applied science“ oriented, medium to bridge natural science, medicinal, regulatory and technical requirements and processes.

Pharmaceutical Industry remains a promising option for Pharmacists.