

## CURRICULUM VITAE



### Summary of expertise

Extensive knowledge in the development, manufacturing and quality management of primary packaging systems especially for syringe systems made out of plastic and glass, including the regulatory requirements for raw materials and finished product.

Active Member of ISO TC 84 Devices for administration of medicinal products and catheters

- WG 3 Needle based injection systems – Injectors, containers and pen needles
- WG 11 Syringes
- WG 13 On-body delivery devices
- WG 15 Device Change Management

and TC 76: Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

- WG 2 Rigid container system and related accessories for parenterals and injectables (Convenor: Horst Koller)
- WG 4 Elastomeric parts and components and related secondary packaging
- WG 6 Primary packaging systems for medicinal products

Swiss Medic Delegate for EDQM WG16 (Pharm Eu. Chapter 3. Plastics)

PDA James P. Agalloco Award for Excellence in Education; March 2019

Since 03/2015

## **HK Packaging Consulting GmbH**

CEO

Extract List of current projects supported by HK Packaging Consulting

- Technical and Regulatory Support for Primary Packaging Manufacturers
  - Choice of Container Material and Components (vials & syringes)
  - Specification Settings / Market Needs & Trends
  - Compendial & Compliance Testing (Pharmacopeias / ISO)
  - Extractables and Leachables Study Proposals
  - Manufacturing Environment Support (Cleanrooms)
  - Certification Support for ISO 15378 / ISO 13485
  - Filing Support (DMF / CTD)
  - Customized Inhouse Trainings
  
- Technical and Regulatory Support Pharma Companies
  - Design Review for submission documents on Combination Products
  - Specification Settings PFS Systems
  - Technical Support / Test Methods PFS / Vials / Cartridges
  - Siliconization Optimization for Cartridges / PFS Systems
  - Syringe Materials / Container Materials / Components Evaluation
  - Compendial and Compliance Testing (Pharmacopoeias / ISO)
  - Design Verification / Design Validation
  - Submission Support
  - Risk Analyses
  - Manufacturing Process (Fill – Finish)
  - Syringe optimization for use in Autoinjectors / Devices
  - Customized Inhouse Trainings

## **Job Expertise**

- 03/2000 – 02/2015 **Schott Pharmaceutical Packaging**
- 2011 – 2015 Head of Technical and Quality Support Syringe Business  
St. Gallen Switzerland
- 2009 – 2011 Global Quality Manager Regulatory Affairs  
St. Gallen Switzerland
- 2007 – 2009 Manager Scientific Advisory  
St. Gallen Switzerland
- 2004 – 2007 Head of Scientific & Regulatory Advisory  
St. Gallen Switzerland
- 2001 – 2003 Manager R&D and Quality Management  
St. Gallen Switzerland
- 2000 – 2001 Head of Product Technology, New Products  
Mainz; Germany
- 1994 – 1999 **ABBOTT GmbH**
- 1995 – 1999 Supervisor Engineering Processes  
Wiesbaden-Delkenheim, Germany
- 1994 – 1995 Research Technician  
Wiesbaden-Delkenheim, Germany

## **Responsibilities; Tasks and Skills**

2000 – 02/2015      **Schott Pharmaceutical Packaging**

- Support of the global syringe business unit regarding questions of technical product requirements, specification and life cycle management
- Support of the global packaging development group for primary and secondary packaging systems in regards to technical, quality and regulatory requirements
- Supporting the stage gate process for new developments including the industrialization phase and roll out of packaging systems to the manufacturing sites
- Participation in cross functional teams: R&D, manufacturing, product management, business development, customer quality etc.
- Participation as Innovation Expert in the Innovation Management Team
- Defining and performing scientific test programs for packaging systems especially for glass and polymer syringe systems including machine and packaging validation.
- Coordination of test programs with external partners for i.e. extractables & leachables, material testing, label migration etc. as technical and regulatory advisor
- Supporting the global business development team with customer education programs and customer visits
- Supporting the global product management, marketing and sales group through technical lectures and product trainings
- Gain knowledge of technical and regulatory trends for primary packaging materials
- Project management for polymer syringes from idea to mass production in Europe and the US
  
- Certification of SCHOTT Schweiz AG according to ISO 9001 and ISO 13485 inclusive annex II and annex V (93/42/EEC) for the SCHOTT TopPac® Syringes
- Drug Master File generation Type III (packaging); US and Canada
- CTD support for ROW customers
- ISO member as technical expert for TC 76 (Syringes) and TC 84 (Needles, Syringes, Needle Based Injection Systems (NIS), Device Change Management)

1999 – 1994

**ABBOTT GmbH**

- Head of process engineering group
- Maintenance, calibration of all equipment for manufacturing and R&D
- Optimization of existing packaging lines for blister, fill & label
- Validation of machines according to GMP guideline
- Leading the cleaning & sterilization centre for glass equipment
- Fermentation and purification of HIV / HCV antigens

**Presentations at conferences**

**A3P**

- Symposium 2001 Biarritz / France
- Protein performance depending on container surfaces

**Concept Heidelberg / ECA**

- Packaging 2011 Mannheim / Germany
- Barriere Verpackung
- 2012 Berlin / Germany
- Barrier Packaging
- 2013 Mannheim / Germany
- Barrier Packaging
- 2014 Berlin / Germany
- Barrier Packaging
- 2015 Vienna / Austria
- Pharmaceutical Packaging Systems
- 2016 Hamburg / Germany
- Delamination
  - Combination Products
- 2016 Mannheim/ Germany
- Glass Packaging
  - Barrier Packaging
- 2017 Heidelberg / Germany

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