Horst Koller
Weinbergweg 1; 8730 Uznach; ☎ (mobil) 079 931 4663

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 an 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

Horst Koller
Weinbergweg 1; 8730 Uznach; ☎ (mobil) 079 931 4663

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 Prdocuts
  - 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

Horst Koller
Weinbergweg 1; 8730 Uznach; ☎ (mobil) 079 931 4663

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

Horst Koller
Weinbergweg 1; 8730 Uznach; ☎ (mobil) 079 931 4663

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 Managemment)

Horst Koller
Weinbergweg 1; 8730 Uznach; ☎ (mobil) 079 931 4663

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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.