

A meeting together with



Food and Drug Administration
of The Islamic Republic of Iran



The Parenteral Drug Association presents...

2016 PDA Europe

Parenterals

**Current Regulatory Guidelines and
Pharmaceutical Technologies**

CONFERENCE GUIDE

**Please
visit our
Exhibition**

6-7 September 2016

Olympic Hotel
Tehran | Iran

pda.org/EU/Parenterals

Silver Sponsor



Scientific Program Planning Committee

Zohre Bazaz, *Conference Chair,
IFDA*

Georg Roessling,
PDA Europe

Dear Colleagues,

Welcome to PDA Europe's first conference in Tehran, Iran. **Parenterals – An Update on Regulations and Manufacturing Technology.** The topics of the agenda were chosen in close cooperation and with the support of the Iranian FDA.

The goal of this conference is to provide attendees with a thorough overview on new regulations and new developments in manufacturing technology especially for Parenterals.

The conference starts with a plenary session on the pharmaceutical landscape in Iran with the general director of the IFDA, Prof. Dinarvand, speaking about the Regulatory Perspective and Framework.

In eight sessions, a broad range of manufacturing aspects will be presented, covering primary packaging components and devices, Blow-Fill-Seal Technology and isolators, fill-finishing operations and freeze-drying, final product testing, labelling and secondary packaging, logistics and good distribution practices. The presentations will address new technologies but also include the latest regulatory and pharmacopoeial requirements.

The conference program has been designed to initiate and support discussion and professional exchange through carefully selected scientific presentations that we believe will foster a vivid interaction amongst all participants.

Hear directly from experts in the field on key issues such as Process Concepts, Equipment and Machine Technology, Components, New Methods and Regulatory Trends. This conference aims to provide a platform to foster a dialogue among the various entities committed to pharmaceutical development, manufacturing, testing and quality assurance.

Following PDA's principles, it is our global aim to provide attendees with sound scientific content as well as the opportunity for discussion and exchange. There is a vendor exhibition, exposing attendees to state-of-the-art machinery and equipment, as well as service providers – all this will surely offer you an excellent opportunity for learning about new developments, keeping yourself up-to-date with current trends and get the opportunity to engage with industry leaders, getting connected and, last but not least, realizing new business opportunities.

Welcome to Tehran!

Best regards

Zohre Bazaz, *Conference Chair,
Food and Drug Administration of
The Islamic Republic of Iran*

Georg Roessling, *PhD,
Senior Vice President, PDA Europe*

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Tuesday, 6 September 2016

9:00 Welcome and Introduction

Georg Roessling,
PDA Europe

9:15 Introduction

Akbar Abdollahiasl,
IFDA

Session 1: Pharmaceutical Landscape in Iran

*Moderator: Georg Roessling,
PDA Europe*

Speakers will focus on the regulatory framework and manufacture's marketing objectives for parenteral products in Iran.

09:30 Regulatory Perspective & Regulatory Framework

Rassoul Dinarvand,
IFDA

10:15 Overview of the Pharmaceutical Market in Iran

Abbas Kebriaezadeh,
*Human Pharmaceutical
Industry Syndicate*

10:45 Q&A, Discussion

11:00 Coffee Break & Exhibition

11:30 Pharmaceutical Science in Iran

Omid Sabzevari,
Associaton of Pharmaceutical Science

12:00 Introduction of Quality System Approach to Pharmaceutical cGMP Resulting in ICH Q10

Saeed Tafreshi,
Intelitec Corporation

12:30 Q&A, Discussion

12:45 Lunch Break & Exhibition, Prayer Time

TRACK A

TRACK B

Session 2

Container & Elastomers

Blow-Fill-Seal

Moderator: **Zohre Bazaz**, *IFDA*

Moderator: **Georg Roessling**, *PDA Europe*

13:45

Glass for Pharmaceutical Applications, Properties and Regulatory Requirements

Bettine Boltres,
SCHOTT

Basic Principles and Regulatory Requirements for BFS-Technology including Qualification and Validation Aspects

Stefan Kiesel,
*Rommelay
Pharma Service*

Session 2		Container & Elastomers		Blow-Fill-Seal	
		Moderator: Zohre Bazaz , <i>IFDA</i>		Moderator: Georg Roessling , <i>PDA Europe</i>	
14:15	High Quality Pre-fillable Syringes – Tailored Syringes for Special Needs in Biotech, Ophthalmology and Home Use		Bernd Zeiss, <i>Gerresheimer</i>	Blow-Fill-Seal Applications	Rajeev Kabbur, <i>Brevetti Angela</i>
14:45	Nested Pre-sterilized Glass Containers: Vials, Cartridges and Syringes		Alessandro Massignani, <i>OMPI</i>		
15:15	Q&A, Discussion				
15:30	Coffee Break & Exhibition				
TRACK A			TRACK B		
Session 3		Container & Elastomers		Isolator Technology	
		Moderator: Bettine Boltres , <i>SCHOTT</i>		Moderator: Georg Roessling , <i>PDA Europe</i>	
16:00	Elastomers		Renaud Janssen, <i>Datwyler</i>	Building Production Capacity for Biosimilars	Stefan Kappeler, <i>M+W Group</i>
	Devices				
16:30	Drug Self-Administration		Thomas Schoenknecht, <i>SHL</i>	- Isolator Technology - Technology & Operational - Handling	André Boesiger, <i>SKAN</i>
17:00	Case Study: How Innovation and Partnership Lead to the Market Launch of a New Self-administered Biotech Drugs in Iran		Hossein Sobhani, Avin Darou, <i>Becton Dickinson</i> Haleh Hamedifar, <i>CinnaGen</i>		
17:30	Q&A, Discussion				
18:00	End of Conference Day 1				
18:15 - 19:30	Networking Reception in Exhibition Area				

Wednesday, 7 September 2016

	TRACK A	TRACK B
Session 4	Aseptic Processing	Regulatory Update
	Moderator: Bettine Boltres , <i>SCHOTT</i>	Moderator: Zohre Bazaz , <i>IFDA</i>
9:00	Aseptic Processing Technology PDA – Points to Consider Annex 1 Georg Roessling, <i>PDA Europe</i>	Computerized Systems Validation Saaed Tafreshi, <i>Intelitec Corporation</i>
9:45	Pharmaceutical Microbiology / Environmental Monitoring Guenther Gapp, <i>Gapp Quality</i>	

10:15 Q&A, Discussion

10:30 Coffee Break & Exhibition

	TRACK A	TRACK B
Session 5	Fill Finish Operations	Utilities
	Moderator: Georg Roessling , <i>PDA Europe</i>	Moderator: Zohre Bazaz , <i>IFDA</i>
11:00	Modern Filling Lines for Aseptic Productions Hans-Christian Gath, <i>Groninger</i>	Water Systems Technology & Regulatory Aspects Guenther Gapp, <i>Gapp Quality</i>
11:30	Multi Product Filling and Freeze Drying Operations Basem Gerges, <i>Optima</i>	
12:00	Container Closure Integrity Jaime Cobo, <i>Wilco</i>	

12:30 Q&A, Discussion

12:45 Lunch Break & Exhibition, Prayer Time

Session 6: Secondary Packaging + Single Use Systems

Moderator: **Georg Roessling**,
PDA Europe

13:45 **Medipak Systems - Integrated Pharma Systems / Solutions - Case Study AICA** Christian Scherer,
Cuba *Medipak Systems*

14:15 **Single-Use Technology in Biopharmaceutical Processing** Ramin Ramezani,
Sartorius

14:45 Q&A, Discussion

15:00 Coffee Break & Exhibition

Session 7 Exhibition & Roundtables

15:05 Guided Tours through the Exhibition Area

15:45 Roundtable Discussion Business Opportunities in Iran

Moderator: **Zohre Bazaz,**
IFDA
Georg Roessling,
PDA Europe

- Mostafa Karimi, *IFDA*
- Amin Motallebyghomi, *IFDA*
- Alireza Hosseini, *IFDA*
- Farid Dorkoosh, *RastaGene*
- Haleh Hamedifar, *CinnaGen*
- Abbas Kebriaezedeh, *Human-Pharmaceutical Industry Syndicate*
- Omid Sabzevari, *Association of Pharmaceutical Science*

16:45 Q&A, Discussion

17:00 Farewell Remarks & End of Conference

Zohre Bazaz,
IFDA

Georg Roessling,
PDA Europe

We thank our Silver Sponsor for the delicious coffee and tea served during the break!

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Representative: Saeed Tafreshi

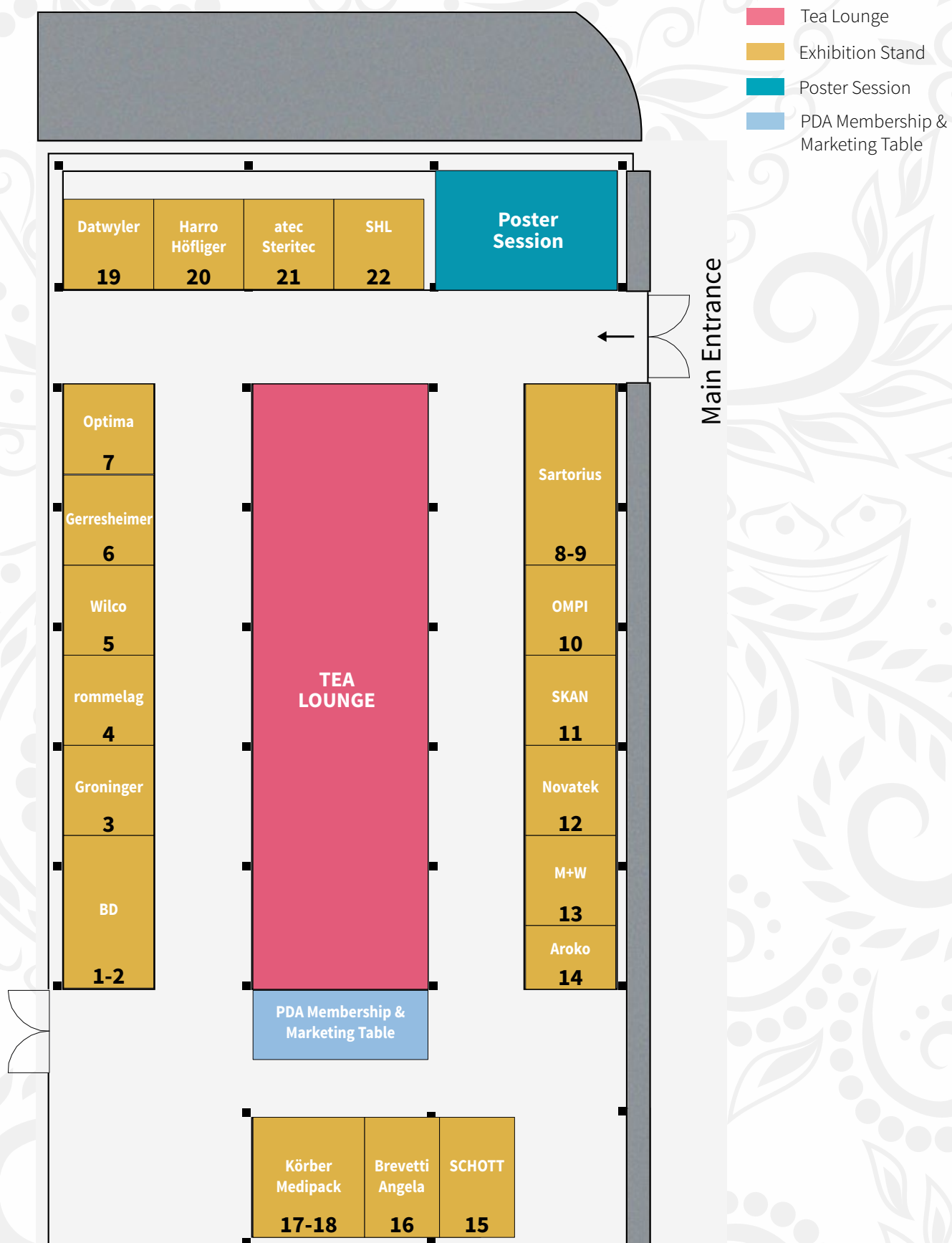
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INTELITEC Corporation, serving the Pharmaceutical, Biotech, Medical Device, and Medical Gas industries by ensuring compliance with FDA regulations through innovative solutions and excellent executions. INTELITEC Corporation delivers valued process validation solutions and related management services to the Life Science Sector. INTELITEC Corporation offers a variety of process validation, compliance and management consulting services in the Pharmaceutical, Biotech, Medical Device, and Medical Gas industries. In all of our services we plan the most efficient path to the best quality results. We achieve this through our focus on engineering an outstanding position in long term quality, while meeting the regulatory compliance and management challenges. Our culture is founded upon striving for continuous improvement with the urgency that ensures the success our customers expect.

FLOOR PLAN

OLYMPIC HOTEL



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Aroko Bioengineering Co. was established in early 2013; based on necessity of the technical knowledge of Bioprocess & biotechnology manufacturing. Aroko Bioengineering Co. has focused on consultation, design, manufacture and installation of process equipment in biotech field, in Iran and Middle-East.

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With ca. 120 employees, a production area of 1.200m² and a modern production facility, including FAT area with clean media supply and automation team, Atec Pharmatechnik offers optimal conditions for the manufacturing of systems / equipment. With a team of experts in engineering, design, construction, automation and qualification, Atec Pharmatechnik GmbH provides comprehensive project support. Atec offers the following products ·Stopper and Cap Processing Systems for the washing, sterilisation, siliconisation and drying of stoppers, plungers, caps and other components ·Formulations systems with mobile or fixed vessels ·Formulation and sterile vessels ·Clean room lifts ·CIP systems Atec Steritec GmbH, a subsidiary of Atec Pharmatechnik GmbH is responsible for sales.

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BD is a medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public. BD designs, manufactures and sells a broad range of medical supplies, devices, laboratory equipment and diagnostic products. BD Medical - Pharmaceutical Systems is the partner of choice for the pharmaceutical industry. With innovative prefillable syringes, self-injection systems, safety systems and needle technologies, we offer an extensive selection of solutions designed to protect, package and deliver drug therapies. Our products reflect more than a century of experience and market knowledge, and our experts provide comprehensive system-based service and full product solutions.

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BREVETTIANGELA was set up in 1977 by Francesco Consolaro, who was already working intensely in the field of pharmaceutical packaging from the 1960s on, to carry out research into packaging techniques and the development of equipment to realise modern primary packaging for parenteral solutions. Since then BREVETTI ANGELA has closely collaborated with many in the pharmaceutical industry to address their needs for primary packaging. The fruits of its intense effort at the cutting-edge of technology are realised in the latest generation of blow-fill-seal equipment series called SYFPACÆ and LIQUIDPAC. Simultaneously, other packaging equipment, viz. FLUIPAC, CYNOPAC, MECAS, BAGPAC and SACKPAC, have also been developed by Brevetti Angela.

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Gerresheimer Bünde supplies a comprehensive range of pre-fillable syringe systems both as bulk products and ready-to-use products. The syringes under our leading trademark Gx RTF® (ready-to-fill) are washed, siliconized, preassembled and sterilized. System components and accessories complete the range and ensure ease-of-use and end-user safety. As an alternative to prefillable Gx RTF® glass syringes we offer COP (Cyclic Olefin Polymer) syringes under the trademarks Gx RTF® ClearJect® and ClearJect®, which meet the requirements of highly demanding drug products.

groninger & co. gmbh

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Filling and packaging machines for the pharmaceutical, consumer healthcare and cosmetic industry. groninger is a successful, experienced and dynamic company with around 1000 employees worldwide, focused on developing and manufacturing specialized machines for accurate filling and secure closing of liquid pharmaceutical products, especially in pre-sterilized syringes, vials and bottles. Working close with the customer, groninger develops and realizes the optimal solution for the customers' requirements! The groninger machine program ranges from: fully automated syringe processing lines with tray loading/unloading, washing, filling, gassing, piston rod insertion, checking, labeling as well as label control with speed up to 60.000/h; liquid filling lines for vials and bottles including washing station, sterilization tunnel, filling, stoppering, labeling, label control as well as capping speed up to 48.000/h; eye drop filling and closing lines with the latest technology and speeds up to 24.000/h; highly flexible filling and closing lines for consumer healthcare, diagnostics and other non-aseptic liquid products in plastic and glass containers; isolator compatible filling machines; peripheral equipment for filling and closing lines, including container and component sorting and feeding equipment and robotic sorting and feeding solutions.

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Medipak Systems is a reliable partner to the international pharma and biotech industry. It unites five successful companies with development and production locations in Germany, Switzerland, the Czech Republic and the US. Medipak Systems offers solutions for save and efficient processes for the production and packaging of pharmaceutical products: these include Pharma Manufacturing Execution Systems (MES), the development and production of standard and special folding boxes, innovative packaging and inspection machines, and solutions for the traceability of medicines. This unique combination of process know-how and advanced technology makes Medipak Systems one of the leading system providers. Medipak Systems unites the companies Dividella, Mediseal, Rondo, Seidenader Maschinenbau and Werum IT Solutions. Medipak Systems is a business area of the Körber Group, a leading international technology group with over 11,500 employees and an annual turnover of more than 2.3 billion Euro.

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**M+W GROUP**

M+W Group GmbH, based in Stuttgart/Germany, is a leading global high-tech engineering company. Established in 1912, the company operates in more than 30 countries. The M+W Group manages projects of all dimensions on behalf of clients from various sectors, including electronics, chemicals and pharmaceuticals, energy and information technology — from semiconductor plants to nanotechnology research centers. The company offers a full range of services from concept and design to turnkey solutions. During the financial year 2015, the M+W Group generated sales of ~3.0 billion euros with around 6,000 employees worldwide.

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Ompi is the Pharmaceutical Systems division of Stevanato Group. OMPI boasts a unique expertise in providing superior pharmaceutical containers from glass tubing. Its comprehensive portfolio covers every customer need, from those related to small molecules to highly sensitive drugs: syringes, pen and dental cartridges, injection and lyophilization vials and ampoules. Syringes, cartridges and vials are produced both in bulk and sterile format (www.ez-fill.com). Ompi EZ-fill concept is a solution that provides the pharmaceutical vials, cartridges or syringes already washed, sterilized ready to be filled by simplifying the traditional production process. Ompi also provides customized containers, all manufactured to the highest standards.

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Optima Pharma develops and manufactures filling, sealing and process technology for pharmaceuticals. Highly sophisticated, fully automated systems from Optima Pharma are used to process blood plasma products, vaccines, oncology and biotech products in prefilled syringes, vials, IV bottles and cartridges. In addition to filling and sealing, complementary functions and process equipment are integrated, including washers, sterilization tunnels and containment systems. Pharmaceutical freeze drying, robotic product handling and clean room technology complete the company's extensive portfolio. OPTIMA Pharma is a member of the OPTIMA packaging group GmbH (Schwaebisch Hall, Germany)

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Rommelag ENGINEERING, the inventor of Blow-Fill-Seal (BFS) Technology, is the worldwide leading manufacturer and supplier of BFS bottelpack® aseptic machines for the packaging of sterile liquids, creams and ointments. Rommelag ENGINEERING also manufactures leak detectors, cap welding machines and inspection systems which can be integrated inline into the packaging system. The machine capacities reach up to 30,000 containers per hour depending on container sizes which vary from 0.1 ml to more than 1,000 ml. Plastic materials used are PE, PP and others. For customer-specific container and closure developments as well as for test and contract fillings own laboratory test and production utilities are available.

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Sartorius Stedim Biotech is a leading provider of cutting-edge products and services for the development, quality assurance and production processes of the biopharmaceutical industry. Its integrated solutions covering fermentation, cell cultivation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry around the world to develop and produce drugs safely, timely and economically. Sartorius Stedim Biotech focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Strongly rooted in the scientific community and closely allied with customers and technology partners, the company is dedicated to its philosophy of "turning science into solutions."

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SHL is the world's largest privately-owned designer, developer and manufacturer of advanced drug delivery devices. We have over 3,000 staff globally, with primary design centers located in Sweden & USA and manufacturing centers located in Asia. Final assembly, labeling and packaging services are also offered in SHL's facility in Florida. SHL supplies auto injectors, pen injectors and inhaler systems to global biopharmaceutical companies. Significant investment in R&D has enhanced our broad pipeline of "next generation" drug delivery systems. These innovative devices include disposable and reusable injectors with fixed or variable dosing, enhanced precision and the ability to accommodate high viscosities.

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SKAN, founded in 1968, is one of the pioneer companies in the field of cleanroom equipment and isolator design for the global pharmaceutical industry. Innovative products, customer-specific solutions and an efficient service organisation have led SKAN to become a global market leader and important partner for industry and research laboratories.

Wilco AG

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WILCO AG provides in-line, off-line and laboratory machines with non-destructive testing methods for monitoring the oxygen content and container closure integrity simultaneously. Our patented leak detection methods based on the process analytical technologies (PAT) offers the opportunity for monitoring the finishing processes as well. We have newly implemented Visual Inspection technologies in our portfolio. With CCIT and Visual Inspection WILCO AG now covers all inspection expectations for pharmaceutical products and our customers benefit from WILCO AG's vast experience in quality inspection.



VENUE

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CONFERENCE REGISTRATION HOURS

Monday, 05 September: 15:00h - 17:30h

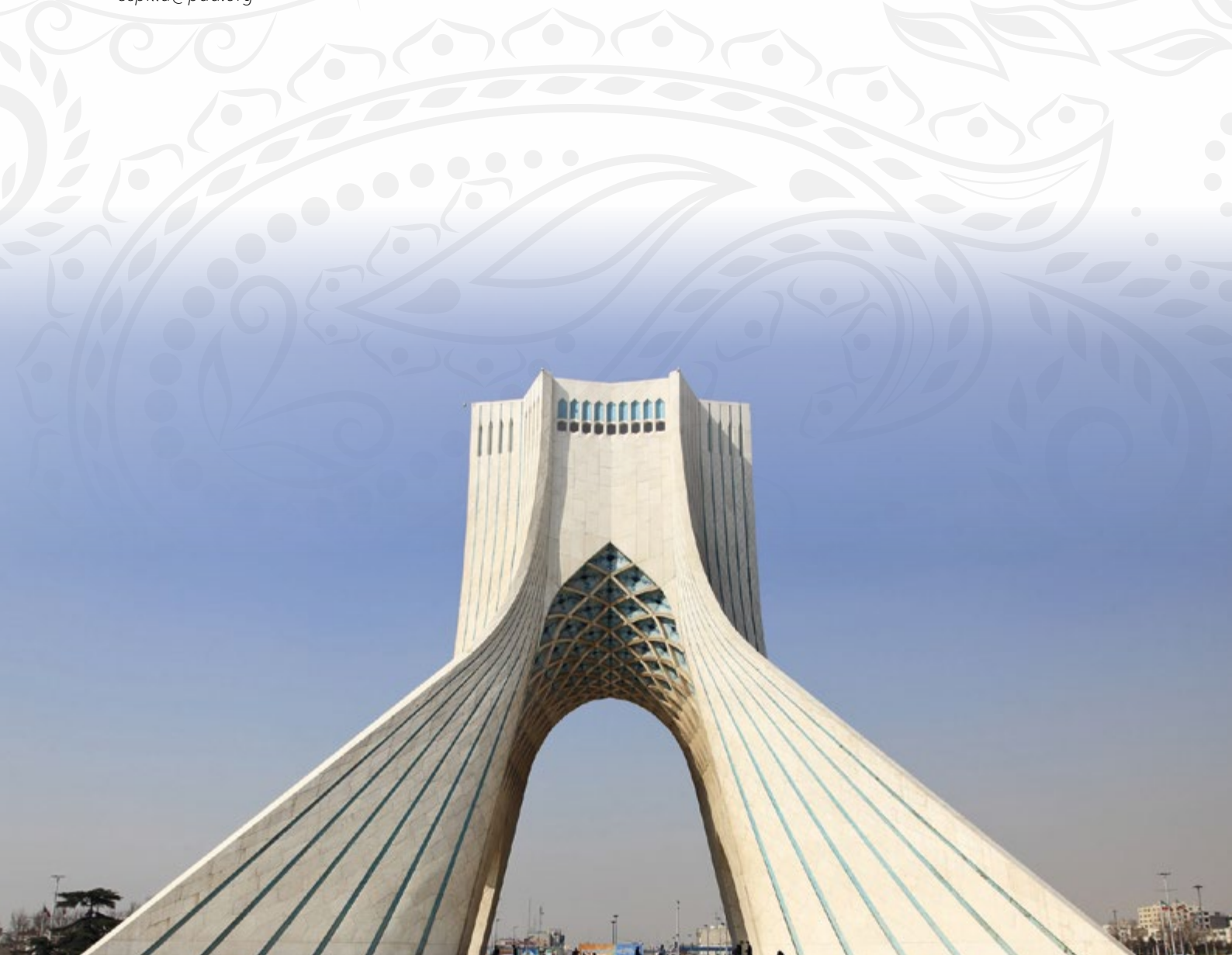
Tuesday, 06 September: 8:00h - 16:00h

Wednesday, 07 September 8:00h - 12:00h

SPECIAL REQUIREMENTS



If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to registration-iran@pda.org.



2016 PDA EUROPE ACTIVITIES & EVENTS

19 September	Smart Devices for Improved Clinical Outcomes	WS	
20-21 September	9th Workshop on Monoclonal Antibodies		
22 September	Elastomers	WS	
22 September	From Gene to Product – Tailormade Strategies for High Level Expression of Biologicals	TC	Rome, Italy
22-23 September	CMC Regulatory Compliance for Biopharmaceuticals	TC	
22-23 September	Extractables and Leachables	WS	
22-23 September	Introduction to Aseptic Processing Principles	TC	
22-23 September	The Metrics of Process Monitoring & Understanding the Risks of Variation	TC	
27-28 September	Pharmaceutical Freeze Drying Technology Conference		
29 September	Application of a Risk-Based Approach to Freeze-Drying Processes	TC	Strasbourg, France
29-30 September	Development of a Freeze Drying Process	WS	
5-6 October	Current Challenges in Aseptic Processing, Potential Changes in EMA/ PIC/ S Annex 1 Revision	WS	Dublin, Ireland
10 October	Schiphol Airport Site Visit & On-Site Workshop “Pharma by Road”		
11-12 October	Pharmaceutical Cold & Supply Chain Logistics Conference	TC	
13 October	Good Qualification Practice of Pharma Storage & Transportation Equipment	TC	Amsterdam, The Netherlands
13-14 October	Secure Cold Chain Practices	TC	
14 October	Outsourcing from API to Drug Product		
24 October	Particle Identification in Parenterals	TC	
25-26 October	Visual Inspection Forum		Berlin, Germany
27-28 October	An Introduction to Visual Inspection: A Hands-on Course	TC	
27 October	Testmethoden für vorbefüllte Spritzen (PFS)	TC	
8-9 November	Data Integrity	WS	Berlin, Germany
14 November	Risk-based Approach for Prevention and Management of Drug Shortages	TC	
15-16 November	Outsourcing & Contract Manufacturing Conference		
17 November	Quality by Design for Biopharmaceuticals	TC	
17-18 November	Practical Guide for Root Cause Investigations – Methodology & Tool Kit	WS	Barcelona, Spain
17-18 November	Outsourcing, Technology Transfer, and CMO-Client Relationships	TC	
17-18 November	Risk Management in Technology Transfer	TC	
17-18 November	Basics of Successful Auditing	WS	
24-25 November	Track und Trace-Implementierung von Serialisierung	TC	Leipzig, Germany

2017 PDA EUROPE ACTIVITIES & EVENTS

14-15 February	Pharmaceutical Microbiology Conference <i>Microbiology in Pharmaceutical Manufacturing</i>		Porto, Portugal
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Subject to change For latest info: europe.pda.org

Shortlist
29. August 2016, 2:47 PM

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Legend
IG – Interest Group Meeting
TC – Training Course
WS – Workshop



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