



International  
Operators  
Association

# BFS IOA Training Seminar 2018

Kunming, China | March 21, 2018



International  
Operators  
Association

# Program *AM session*

- Welcome & Introduction
- Introduction to BFS, Background and History
- Regulatory Aspects of BFS Production  
- including environmental monitoring
- Qualification and Validation of BFS Installations  
- CIP / SIP, Visual inspection, IPC, Leak testing
- Lunch



International  
Operators  
Association

# Program *PM session*

- Validation of Aseptic Fill Process / Media fills
- Autoclaving of BFS Products  
- including Validation
- BFS Machine Maintenance
- Down-stream Handling and Secondary Packaging
- Filling of Heat sensitive Products/Biologicals with BFS
- Summary and panel discussions



International  
Operators  
Association

# Presentation of BFS IOA

- The Pharmaceutical Blow-Fill-Seal International Operators Association (BFS IOA) is an international industry association for pharmaceutical and associated companies, which have a direct or indirect involvement with Blow-Fill-Seal (BFS) manufacturing.
- BFS IOA is a non-profit organization, and is financed by subscription of more than 60 member companies worldwide and by sponsorships from the industry.



International  
Operators  
Association

# History of BFS IOA

- In 1988, the BFSIOA was established as an interest group of pharmaceutical and associated companies actively involved with BFS processing.
- The Association was formed to provide its members with an opportunity to exchange ideas and opinions, and to formulate agreement on operating standards.
- It also provided a forum to speak with a unified voice to machine manufacturers, commercial suppliers, and regulatory bodies.
- Over the years the Association has expanded worldwide and now has over 60 member companies.
- To date the Association has members from Europe, the Americas and Asia.



International  
Operators  
Association

# BFS IOA Mission

- To **educate** pharmaceutical industry and regulatory bodies around the world **about BFS technology**
- To **promote common understanding** worldwide on how BFS technology should be applied
- To **educate members** about current and proposed future **guidelines relevant to BFS technology** to ensure continuous regulatory compliance
- To **facilitate networking** between BFS experts and peers on technical and regulatory matters
- To offer a platform where operators will be updated on **new developments** related to BFS technology



International  
Operators  
Association

# Scope of activities

- Meetings (Europe, America and Asia/Pacific)
- Communication (website, newsletter, PR leaflet)
- Points to Consider (March 2012 edition)
- Organisation interaction (PDA IG, PDA Europe)
- Training seminars
- Technical work (PDA Task force)
- Sponsor of academic work
- Member administration



International  
Operators  
Association

# The BFS IOA Board for 2017

- Peter Åkerman, AstraZeneca, Sweden  
*Chairman*
- Martin Haerer, Rommelag CMO, Germany  
*Regulatory Officer*
- Kevin Downey, Teva Runcorn, UK  
*Technical Officer*
- Jesper Laursen, MELITEK, Denmark  
*Officer of Operation*
- Bill Hartzel, Catalent Pharma Solutions,  
USA  
*Appointed Officer*





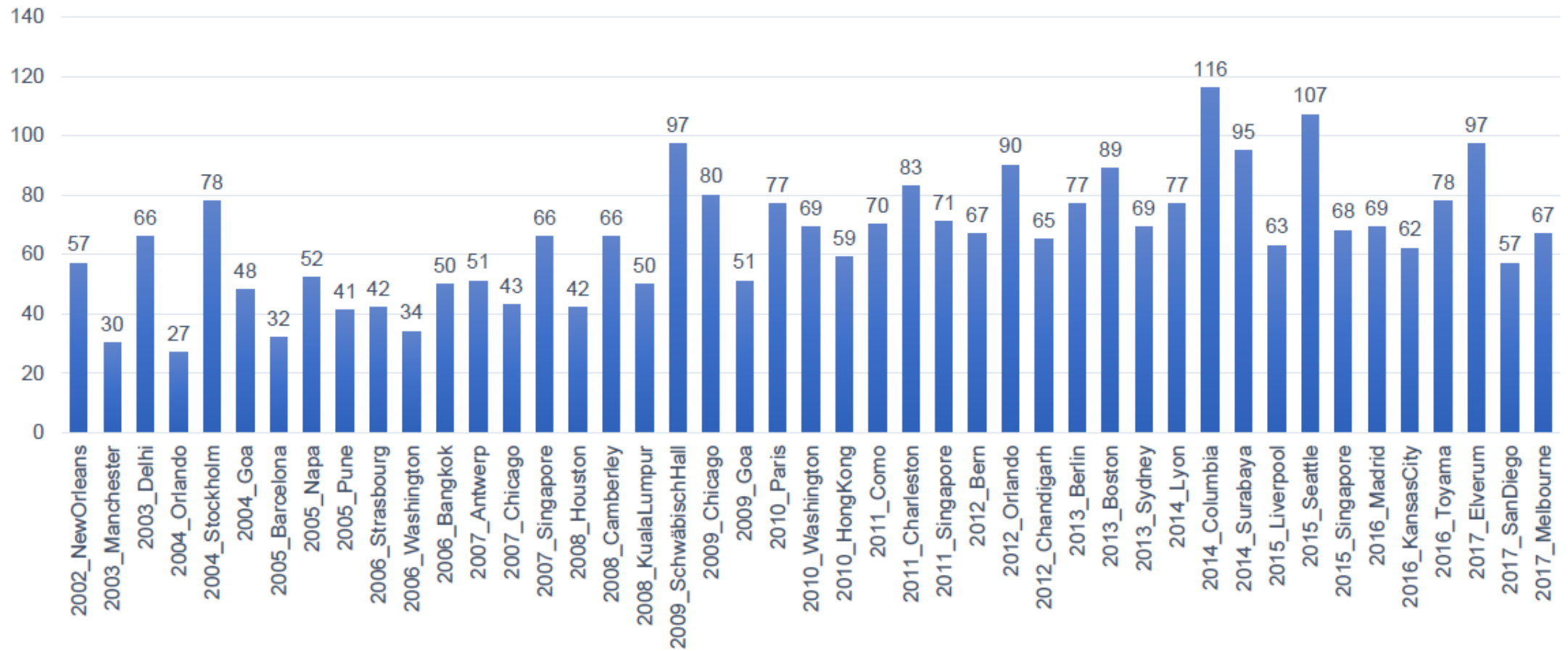
International  
Operators  
Association

# Meetings in 2017

- European meeting and AGM 2017  
Elverum, Norway, June 20-21<sup>st</sup>  
*(including site visit to the 'Curida' plant)*
- American meeting 2017  
San Diego, September 27<sup>th</sup>-29<sup>th</sup>
- Asia/Pacific meeting 2017  
Melbourne, Australia, November 8<sup>th</sup>- 9<sup>th</sup>  
*(including site visit to the 'Glaxo, GSK, plant)*



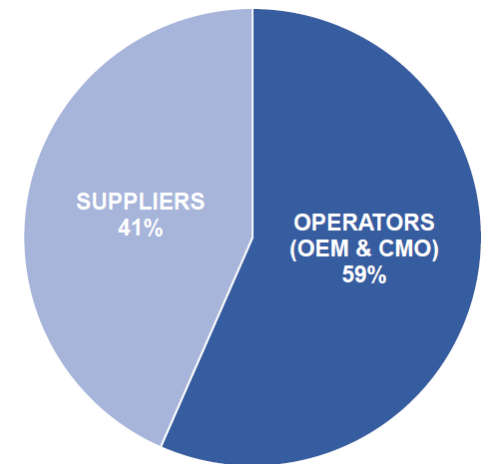
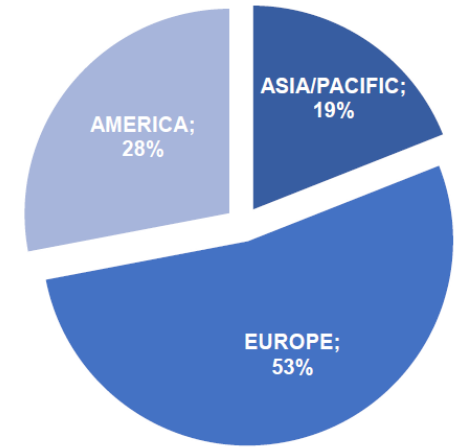
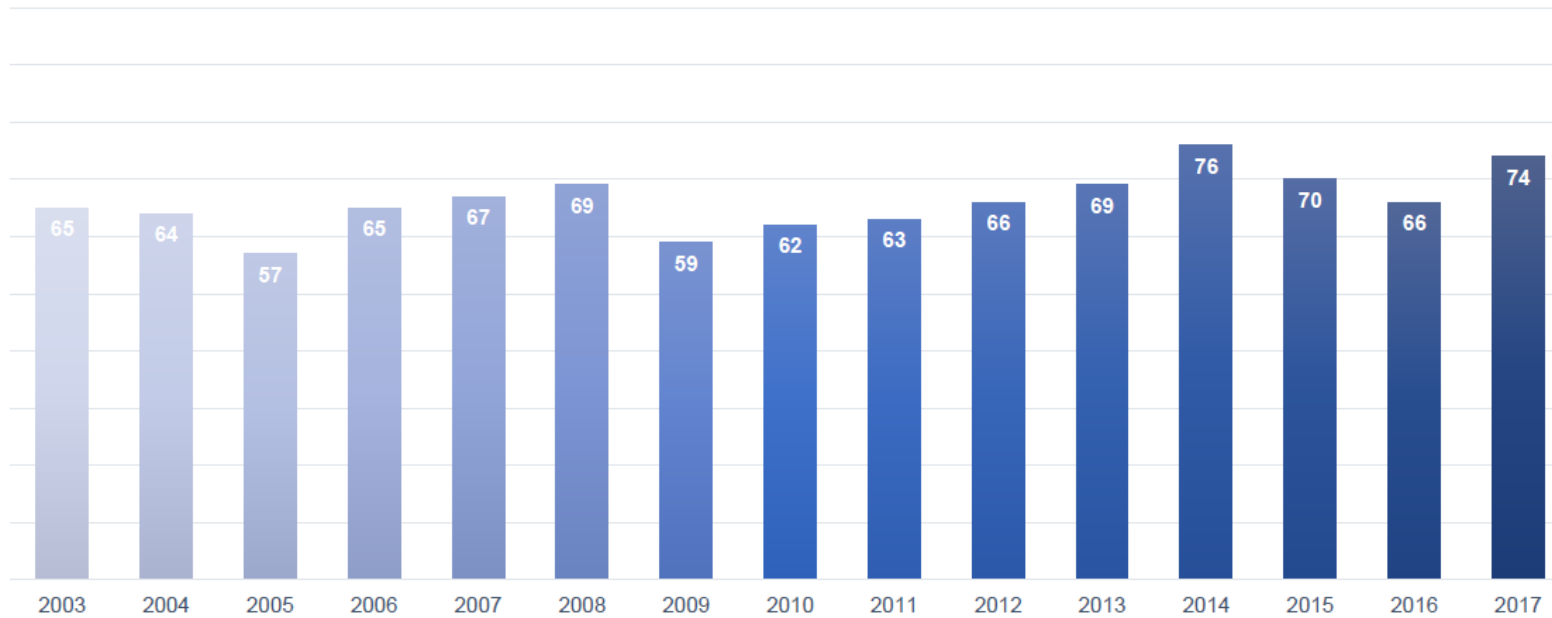
# Meetings – Participants stats





International  
Operators  
Association

# Members





International  
Operators  
Association

# Achievements 2016 / 2017

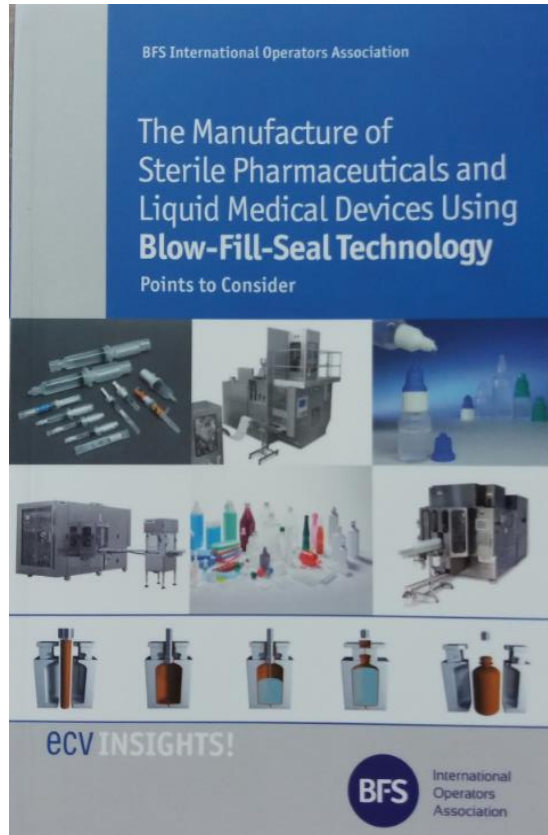


- Cooperation with PDA has resulted in the new PDA Technical Report TR 77 for BFS!
- First time an official guidance document for Manufacturing by BFS Technique
- The TR can be purchased from PDA for \$ 150 (PDA members)  
\$ 325 (non-PDA members)



International  
Operators  
Association

# Achivements 2016 / 2017



- Cooperation with ECV regarding printing and official release of a booklet based on our "Points to Consider"
- Can be purchased from the publisher or directly from BFS IOA for 19,95 € / 25 US \$



International  
Operators  
Association

# Scientific / Academic work

- BFS IOA can offer Scholarships to Students at Universities for BFS related studies
- We will be sponsoring a scientific work about Fluid Dynamics together with the Monach University in Melbourne. This can be of great value for the BFS community !



International  
Operators  
Association

# Presentation

More information about the BFS IOA  
can be found on our webpage :

[www.bfsioa.org](http://www.bfsioa.org)