



## **Annual Report for 2018 from the BFS IOA Chairman**

**Dear BFS friends,**

Like usually in this season of the year, it is time for me to send an Annual Report to you about what we achieved in the Association last year, and give you a glimpse of what will happen in 2019.

This year, I'm especially excited to welcome you all to Stockholm, the beautiful capital of Sweden, where we will have our traditional Annual General Meeting. The town is often called "Venice of the North" since it's founded on several islands where the Lake Mälaren, (the third biggest lake in Sweden), meets the Baltic sea.

I'm also happy to welcome you to a site visit to AstraZeneca's extensive BFS manufacturing plant, located about 30 km south of Stockholm. This is where I spend my daily business, still learning new knowledge around the BFS technology that keeps us all together.

### **Milestones in 2018**

When I sent out the Annual Letter for 2017 last year, I was very proud to look back on all the fantastic achievements we had that year; for example the finalisation of the PDA cooperation that resulted in the now well-established Technical Monograph TR-77 around BFS Manufacturing, the booklet we published together with ECV, the Scientific work at the Monash University we agreed to support and also our first Training Seminar in China in beginning of 2018. Although we this time must look back on a more traditional year, I anyway consider 2018 to have been another successful year for our Association;

- We were able to offer nice site visits to all our three meetings.
- We reached an 'all time high' number of attendees at our meetings.  
In total more than 360 persons came to learn more on BFS during 2018 !  
(the training seminar in China in March 2018 not included!)
- We got more than ten new member companies  
(Since some former members unfortunately didn't prolong their membership, this in the end only resulted in a minor increase of total members).

Regarding our initiative to support the study of Computational Fluid Dynamics at the Monash University in Melbourne, we had to accept a delay in the start of the work. Beside the sponsorship from BFS IOA, the scientific team also applied for grants from the local government in the Victoria State. This process took longer time than expected, and in addition, the scientific leader at Monash, Dr. Meng Wai Woo, moved to a new position at the University of Auckland in New Zealand.

On the positive side, there will be a new leader of the planned work in Melbourne, where the study will be transferred to the Deakin University instead. We have established a contact with the new leader, Sara Vahaji, PhD, who is lecturer in Mechanical Engineering. Our intention is now to sign a new agreement with them instead, still including the same scope as was agreed initially with the Monash University.

In 2018, the Board of the BFS IOA sent in comments to the EMA regarding the chapter on Blow-Fill-Seal Technology in the draft for the revision of the EMA GMP, Annex 1 "Manufacture of sterile medicinal products". As you all probably are aware of, the new version is still not being issued, and we have not got any comments to our suggestions of changes in the text. Therefore, we will have to continue to wait for this.

## **Meetings in 2018**

Also during 2018, we have as normal arranged three meetings, one in each region Europe, America and Asia/Pacific.

The European meeting, that also was our Annual General meeting for 2018, was held in Colmar in the beautiful region of Alsace in France on May 14-16<sup>th</sup>. The meeting attracted the highest number ever of participants to one of our meetings, 141 attendants! Beside the lovely landscape, the scenery of historic houses and the delicious French food, of course also the nice BFS plant of Recipharm in the nearby town Kaisersberg was the reason for this fantastic number of participants. During the tour in the factory, we got the opportunity to see how a former warehouse had been converted to a new production area where a brand-new production just had been installed.

We also got the chance to finalise the first meeting day with a traditional BFS boat tour, this time on the river Rhine. Thanks to perfect arrangements by Recipharm and our Communication Assistant, Mrs Tine Damgaard, the shipping company was "BFS" !



In September 25-27<sup>th</sup>, we arranged our Asian meeting 2018, this time in a new very exciting area where we never had been before. We went to Uzbekistan, where the meeting was held in the modern city Tashkent. Instead of a boat tour, we this time went for a very nice bus tour through the central parts of Tashkent, during which we visited many impressive and beautiful buildings and places.

Thanks to a huge interest from members and invited guest in the country and from several surrounding countries, we attracted 127 persons to the meeting. This was more

than we had expected, but once again it shows what a huge interest there is to learn more about BFS in most areas of the world.



Uzbekistan is a country that is developing fast, and therefore the supply of high-class pharmaceutical products, preferable made by BFS technique, is important. During our stay in Uzbekistan, we were invited to visit two different BFS operators, Jurabek and Dentafill. The hospitality we met from both companies were most impressive, and we were served both a lot of tasteful local food and traditional music in the factory parks before the tour in the manufacturing.

We ended the BFS year 2018 by travelling to Florida in USA, where we stayed in Fort Lauderdale December 5-6<sup>th</sup>. The venue was The Diplomat Beach Resort nicely situated at the beach, where we had a fantastic view out of the Atlantic Ocean. Also to this meeting, we had more than 100 attendees coming. The figure of 107 participants is similar to the former 'all time high' for a US meeting that we had in Seattle in 2015. Once again, we were happy to offer our members the opportunity to have a interesting site visit, since we were kindly invited to the inauguration of the brand new facility of Unipharma in Tamarac City. The BFS dinner was then served in conjunction to the traditional boat tour that we made on a part of the long Intracoastal Waterway that goes along the coast of Florida.



Like every year, the topics have varied from one meeting to another, and thus a wide range of topics has been covered during the year. There have also been open and good discussions during the meetings, and when you as our members are sharing experiences, and we try to find a common base level for the future, we can develop the application of the BFS technology even further.

I also want to take the opportunity to express my sincere gratefulness to the sites for inviting the BFS community to come to visit their facilities. And of course, I also want to say thank you for the all the perfect treatment we have received regarding food and refreshments before and after the visits. During these site visits, we have appreciated the openness we have met, but we also felt the great pride of the companies who have got the possibility to show their philosophy around BFS production. I hope this will inspire other companies to show their production facilities in the future. We have a lot of common interests in the rather small BFS world that we can share and support each other with.

### **Some words about the AGM in 2018**

Our Officer of Operation, Mr. Jesper Laursen, presented the accounts for 2017 as well as the budget for 2018. They were both approved by the present members. There were also voting for two positions of the Board, Technical Officer and Officer of Operations. For these positions, the present holders were re-elected for a new term of two years.

In addition to this, I'm also very happy to inform that the Board have decided to appoint Christophe Schwoehrer from Recipharm in Kaysersberg, France as a new Appointed Officer, a position that Christophe kindly has accepted.

This gives me the opportunity to present the Board for BFS IOA for 2018/2019;

- *Chairman:*  
Peter Åkerman, Senior Adviser, AstraZeneca, Sweden,
- *Technical Officer:*  
Kevin Downey, Head of Quality, TEVA Runcorn, UK, (*re-election*)
- *Regulatory Officer:*  
Dr. Martin Haerer, Senior Director R&D/Qualified Person Rommelag CMO, Germany,
- *Officer of Operation:*  
Jesper Laursen, Business Director, MELITEK, Denmark, (*re-election*)
- *Appointed Officer:*  
Christophe Schwoehrer, Project Manager, Recipharm, France (*new*)
- *Appointed Board Member for US:*  
Bill Hartzel, Vice President, Business Development, Respiratory & Ophthalmic Catalent Pharma Solutions, NJ, USA

### **The new BFS IOA year 2019 – what will happen ?**

It is only a few days left until we welcome all our members to our AGM and European meeting for 2019. As I mentioned in the introduction, this will take place in Stockholm on June 17-19<sup>th</sup>, where we will stay at Elite Hotel Marina Tower. The hotel is situated just by the harbour, and I can guarantee that you will have a fantastic view of the City, the famous Old Town, the museum and amusement island 'Djurgården', and of course all

the boats passing by. They are of all sizes from small motorboats, passenger boats serving the islands in the archipelago, ferry boats to other countries and up to huge cruising ships.

On the first day, Monday 17<sup>th</sup>, we will introduce a new initiative. We will for the first time arrange a workshop open only for Operators of the BFS technology. The topic we have selected for the workshop is to discuss how to find the best practise for media fills. This is a matter that Inspectors always are most interested in, and therefore we are sure that this will be a suitable topic. By limiting the number of participants to only 40, we hope to get a more open discussion than we normally have had in earlier workshops.

On Tuesday 18<sup>th</sup>, we will go by bus to the town Södertälje, where AstraZeneca has it's major production site with more than 3500 people employed. Before visiting the BFS production area in the afternoon, we will have a range of presentations in a lecture hall belonging to the Royal Institute of Technology, who opened a new campus in there just one year ago. During the factory tour, you will have the opportunity to see some recent installations of high automated manufacturing lines suppling AstraZeneca products globally.

After the site tour, we will enter an lovely old, former steam boat, that will take us back to the hotel by sailing on the Lake Mälaren back to Stockholm. While you we see the beautiful Swedish landscape passing by, you will be served a BFS dinner with Swedish specialities.

Then on Wednesday June 18<sup>th</sup>, we will continue at the hotel with more presentations, and finalise the day with the formal AGM meeting. Among other items, you will there get the chance to review and approve the **Accounts for 2018**, and vote on the proposal for **Budget for 2019**. There are two of the positions in the Board up for election; Chairman of the Board and Regulatory Officer. The current holders of the positions are available for a new term and thus nominated by the board, but of course we welcome other suggestions for candidates. If you have a recommendation for a candidate, please let me know, so we can add that name to the voting process. We have also updated the **Rules of the Association**, and they will be available for you to comment on at the meeting.

The agenda for the meeting is available on our web-page, and I hope the mixture of different topics will offer everyone to find several interesting presentations. I can also inform you that it seems like we will once again have a new 'all-time-high' when it comes to the number of attendees. A few days ago, we were already far above 130, so if you haven't signed up yet for the meeting - please hurry up !

Regarding the two remaining meetings in 2019, we go back to normal order, that means we will arrange our US meeting in September, including a site tour at Amcor's production plant in Asheville, NC. The BFS year 2019 will then end in Hong Kong, where we decided to set up our Asia/Pacific meeting.

### **Some final words**

As every year, I once again want to encourage you all as members to come up with suggestions for topics that you want us to put more attention to in our programs. And,

even better, if you have something you want to present from your own experience that will be even more appreciated! You are always welcome to us in the Board to discuss any ideas that can contribute to return a better value for the BFS community.

Finally, I want to thank you all for your interest in the Association during 2018, and I hope you will continue to support the Association with your membership also in 2019.

On behalf of the whole BFS Association, I want to take the opportunity to express our sincere gratitude to all our valuable Sponsors for their important contribution to our mission.

Most welcome to the meeting in Stockholm, and looking forward to see you there!

Best personal regards

*Peter Åkerman*

Peter Åkerman  
Chairman of the board BFS IOA  
June 2019

*PS. I hope you will consider prolonging your visit to Stockholm with some additional days. This will give you a chance to explore some of all the nice things worth seeing here. For example, the Royal Palace, situated on the small island today called "the Old town" where Stockholm was founded in 1252. It is lovely to take a walk there in the narrow alleys among houses preserved from the 16th century. Other famous places to visit are the City Town Hall, where the Nobel banquet is arranged every year, and of course you must not miss the Wasa museum. That is where the nowadays world known former warship Wasa, that sank in the Stockholm Harbour in 1628, now has been restored. And of course, even if you are not interested in old houses and museums, you can still just enjoy the long light summer evenings when it never becomes dark. DS.*

