



BLOW FILL SEAL TECHNOLOGY: STATE OF THE ART FOR THE ASEPTIC PRIMARY PACKAGING OF PARENTERALS

July 04-05, 2024

Brevetti Angela, Arzignano (VI); Villa
Cordellina, Montecchio Maggiore (VI)



INTRODUCTION



PDA Italy Chapter is pleased to announce “BLOW FILL SEAL TECHNOLOGY: STATE OF THE ART FOR THE ASEPTIC PRIMARY PACKAGING OF PARENTERALS” in association with Brevetti Angela on 04-05 July 2024. Two days fully dedicated to latest developments in the Blow-Fill-Seal technology and the manufacture of sterile pharmaceutical products with a deep focus on the impact of new regulations, on the challenges and advantages faced when filling pharmaceutical products in plastic, and on the possibilities given by such a process compared to traditional filling.

At this event, we will present and discuss new developments and expectations in BFS, which continues to be critical for the packaging of parenterals with high speed and reduced cost. This applies to small volumes for injectables, ophthalmics, sprays, but also to prefilled syringes and to large volumes like IV solutions.

Starting from the regulatory scenario, which continues to evolve rapidly with new or revised guidance, we will see how Annex 1 new requirements are met within the Blow Fill Seal process with a case study about vaccine filling.

We will examine the differences between traditional filling in glass ampoules and BFS, understanding pros and cons directly from the voice of a pharmaceutical company who has been using this technology for more than a decade.

We will also analyze the role of plastic in primary packaging, with special attention to medical grade granules and sustainability. Special attention will be given to the matter of extractables and leachables, and to the role of Container Closure Integrity Testing and Visual Inspection.

The conference will be held in the splendid setting of Villa Cordellina Lombardi, an Eighteenth-century palace that combines the Palladian elegance with Baroque forms. The presentations will be given under Tiepolo’s frescoes of the main hall and the coffee breaks will be held in the elegant garden of the villa. The workshop will be arranged at Brevetti Angela’s plant for all practical activities, where we will visit the production area and we will have the opportunity to see a BFS machine in operation.

This will also be a wonderful opportunity for exhibitors to present themselves and their product and service portfolio, as a dedicated time slot has been added to the agenda for this specific purpose.

ORGANIZING COMMITTEE

Andrea Simonetti (Consultant)
Massimo Consolaro (Brevetti Angela)
Rajeev Kabbur (Brevetti Angela)
Filippo Trionfera (BSP Pharmaceuticals)
Lucia Ceresa (Charles River)
Mirko Gabriele (InfiniteVision)
Gabriele Peron (Stevanato)

AGENDA DAY 1 – July 04th, 2024



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|-------------|--|
| 11:00 | First meeting point at Verona Porta Nuova train station and transfer by bus to Hotel Crowne Plaza |
| 11:30-11:45 | Overall meeting point at Hotel Crowne Plaza lobby and transfer by bus to Villa Cordellina |
| 13:00-14:00 | Arrival, registration & Welcome buffet |
| 14:00-14:15 | <i>Opening remarks and proposed discussion topic</i>
Mirko Gabriele , Consultant and PDA Italy Chapter President |
| 14:15-14:30 | <i>Welcome and Introduction</i>
Rajeev Kabbur , Brevetti Angela Director of Sales and R&D |
| 14:30-15:00 | <i>Overview of the regulatory aspects and requirements related to BFS – EU GMP Volume 4 Annex 1, PTC BFS IOA, PDA TR 79;</i>
Andrea Simonetti , Consultant |

AGENDA DAY 1 – July 04th , 2024

- 15:00-15:30 *Evolving your Fill and Finish Process to Blow Fill Seal*
Lellos Argyris, Demo, **Rajeev Kabbur**, Brevetti Angela Srl
- 15:30-16:00 *Design of an aseptic filling line in accordance with new Annex 1,*
Mattia Ricchini, CSV Life Science, **Ajay Kabbur**, Brevetti Angela S.r.l.
- 16:00-16:15 **NEWS from the SPONSORS**
- 16:15-16:45 Coffee Break at the sponsors area
- 16:45-17:30 Points-to-consider for the Qualification and validation of BFS processes, **Claudio Puglisi**, Entourage
- 17:30-17:45 **Panel Discussion** with all speakers, chairs: **Fernanda Ferrazin – Life Science Consultant, former Senior AIFA GMP Inspector and Marisa Delbò, former AIFA Senior GMP Inspector**
- 17:45-18:00 Wrap-up and Closure of the 1st day

Pickup and transfer to Hotel Crowne Plaza by bus provided by Brevetti Angela

Networking dinner at HotelCrowne Plaza

AGENDA DAY 2 – July 5th , 2024

- 07:45 Meeting point at Hotel Crowne Plaza lobby
- 08:00-9:30 Transfer by bus to Villa Cordellina
- 9:30-10:00 *Medical grade plastics and the challenges of sustainability*
Anja Gottschalk, Borealis Group
- 10:00-10:30 *Extractables & Leachables Testing of BFS Ampoules'*
Iris Destoop, Nelson Labs
- 10:30-11:00 Coffee Break at the sponsors area
- 11:00-11:30 *BFS Applications and new developments: squeezable syringes*
Massimo Consolaro – Brevetti Angela
- 11:30-12:00 *BFS Containers Automatic Visual Inspection & Leak Detection; Particle identification, characterization and definition of control strategy*, **Matteo Falcone**, Antares Vision and **Atanas Koulov**, Clear Solutions Laboratories
- 12:00-12:30 *Blow Fill Seal Technology – GMP Inspection prospective, Panel Discussion with all speakers, chairs: **Fernanda Ferrazin** – Life Science Consultant, former Senior AIFA GMP Inspector and **Marisa Delbò**, former AIFA Chief GMP Inspectorate*
- 12:30-13:30 Lunch
- 13:30-13:45 Transfer to Brevetti Angela plant
- 13:45-15:00 Manufacturing tour: splitting into groups of about 15 people and visit of the with BFS machines in-operation
- 15:00-15:15 Transfer from Brevetti Angela facility to Villa Cordellina
- 15:15-15:45 Coffee Break
- 15:45-16:15 Round table discussion
- 16:15-16:30 Wrap up and closing remarks
- 16:30-17:00 Transfer to Hotel Crowne Plaza

NOTES Transfers from Hotel Crowne Plaza to Facilities and back will be arranged by Brevetti Angela based on the scheduled timing. Participants are responsible for organizing and paying their own travel costs and accommodation to the Hote

GENERAL INFORMATION

HOW TO REGISTER

For registration, general information and payment enquiry, please visit www.pda-it.org at the page dedicated to the Event.

REGISTRATION FEES (VAT 22% included)

€ 122,00	University and Regulators
€ 366,00	PDA member
€ 549,00	PDA NON-member
€ 732,00	for 2 colleagues for the conference at the same time
€ 1.038,00	for 3 colleagues for the conference at the same time

Early bird discount: **10% discount** for confirmation received within **31/03/2024**

Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, coffee breaks, lunches, networking dinner.

METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl

Bank: INTESA SANPAOLO SPA

Mandatory causal: **C009/24** + Name/Surname of the participant and Company

IBAN: IT08X0306901000100000067336

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Copy of the bank transfer should be sent to the Organizing Secretariat at pda@pda-it.org. After receiving the payment, the Organizing Secretariat (Centro Congressi Internazionale srl) will issue a regular invoice.

SPONSORSHIP OPPORTUNITIES

Exhibition and Sponsorship Opportunities are available. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees. Contact the Organizing Secretariat at pda@pda-it.org to know the opportunities for this event.

GENERAL INFORMATION



LANGUAGE

The official languages are Italian and English. No simultaneous translation is provided. The presentations (ppt slides) will be in English.

CONGRESS VENUE

VILLA CORDELLINA LOMBARDI

Via Lovara 36, 36075 Montecchio Maggiore (VI)

MANUFACTURING PLANT TOUR at BREVETTI ANGELA SRL

Via Seconda Strada 48

Via Industria 99

Arzignano (VI)

info@brevettiangela.com

CONVENTIONED HOTEL

Crowne Plaza Hotel, via Belgio 16, 37135 Verona

PDA Events & Organizing Secretariat



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