

**Event:** TAMPA 2011 CONFERENCE  
**Session:** Syringe Processing Workshop, 2nd Annual  
**Session Leader:** Nancy St. Laurent; Joerg Zimmerman  
**Dates:** Wednesday-Thursday 23-24 February 2011  
**Location:** Tampa, FL  
**Web Link:** <http://www.ispe.org/2011tampaconference/syringeprocessing>



## Wednesday, 23 February

| Start Time | End Time | Presentation Title  | Speaker Full Name | Speaker's Company       | Total min. |
|------------|----------|---|-------------------|-------------------------|------------|
| 7:00       | 8:00     | Speaker / Leader Breakfast (invitational)   |                   |                         |            |
| 7:30       | 9:00     | Breakfast   |                   |                         | 60         |
| 9:00       | 9:15     | <b>Welcome and Overview</b><br><b>Prefilled Syringes: Market Overview 2011</b><br>In this presentation, the current situation in the market of prefilled syringes is layed out. What is happening in the market of injectables? What dosage forms are growing? What is happening in the emerging markets? What is happening in the field of pens and autoinjectors? All this is supported by latest market data. Finally, an outlook into what is going to happen over the next few years is given.   | Joerg Zimmerman   | Vetter                  | 15         |
| 9:15       | 10:00    | <b>The Use of Fracture Analysis Techniques to Solve Breakage Problems</b><br>A breakage problem in the filling operation or even worse in the field, can lead to lost time, recalled/rejected ware and other serious problems. In order to deal with the current issue, as well as prevent the problem in the future, it is necessary to understand the root causes responsible for the breakage. Fracture diagnosis techniques can be used to determine the conditions leading to the breakage and to distinguish between breakage due to glass manufacturing problems verses that due to improper handling or usage, and the manner in which fracture diagnosis techniques can be used to evaluate four distinctly different types of breakage. | David Machak      | American Glass Research | 45         |
| 10:00      | 10:30    | Networking Break  |                   |                         | 30         |
| 10:30      | 11:15    | <b>Silicon Deposition Optimization in PFS and Real-time Control of Distribution and Droplet Size</b><br>Silicone oil is suspected of triggering the aggregation of protein and generation of sub-visible particles. Recently techniques for controlling the deposition of silicon oil, droplet size and layer thickness designing special nozzles and characterizing the aerosol spray by digital imaging have been studied. Also glass suppliers have been studying the role of glass surface. This presentation focuses on the different techniques available for measuring the silicon layer identifying the most suited for in-line integration.  | Howard Drake      | Nuova Ompi              | 45         |

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|-------|-------|--|--------------------------------------|----------------|-----|
| 11:15 | 12:00 | <b>Difficulties with Multi Product Specification</b><br>The implementation of filling equipment is challenging as business requirements are dynamic and specifications are written at a snapshot in time. Appropriateness of machine design is heavily dependent upon the requirements of the end user, and as those requirements vary or change once the design has been finalized, the start-up time for the equipment is impacted. The operability and consistency of equipment at the limits of the design range presents unique challenges for implementation. Time Pressure Filling (TPF) requires specific knowledge about the attributes of the material being filled. As aspects such as fill volume or product family change as a result of market demand, or for any reason, the implementation of the equipment becomes challenging. The worldwide pandemic which occurred in 2009 caused priority to be focused on larger volumes of vaccine. As this volume increased, it pushed the limits of the equipment design. | Allison Cacciatore                   | sanofi pasteur | 45  |
| 12:00 | 13:00 | Lunch  |                                      |                | 60  |
| 13:00 | 13:45 | <b>Potent Syringe Filling Line</b>   | Brant Bulgarelli                     | BMS            | 45  |
| 13:45 | 14:45 | <b>Amgen-Glass Breakage and Puerto Rico Facility</b>   | Sharon Wu                            | Amgen          | 60  |
| 14:45 | 15:15 | <b>Networking Break</b>  |                                      |                | 30  |
| 15:15 | 17:00 | <b>Workshop</b><br>As last year, there will be an interactive workshop with a case-study. The audience will be divided into small groups to work on a little project. <i>This project could be: Design a small-scale syringe filling operation to support clinical supply. Take into consideration packaging material, operational aspects as well as aseptic and quality assurance topics.</i> The results from the individual groups will be presented back to the full audience.  | Joerg Zimmerman<br>Nancy St. Laurent | Vetter Parsons | 105 |
| 17:00 | 17:00 | Seminar Adjourns, Reception [Note Tomorrow starts at 8:00!]  |                                      |                | 0   |

## Thursday, 24 February

| Start Time | End Time | Presentation Title  | Speaker Full Name | Speaker's Company | Total min. |
|------------|----------|---|-------------------|-------------------|------------|
| 7:00       | 8:00     | Breakfast   |                   |                   | 60         |
| 8:00       | 9:00     | <b>Packaging Case Study</b><br>Filling the syringe is only the first step in the path to assembling a device that is intended for point of care use. Harro Hofliger Packaging will share some of the challenges companies need to be aware of when they opt for an automated assembly solution for their device. In addition, customer experiences outlining their own internal struggles with the development of a device, planning for a site and installation of equipment and lastly preparation for market launch are covered. | Robert Gervais    | Harro Hofliger    | 60         |
| 9:00       | 9:45     | <b>Case study: High-speed filling line for presterilized syringes</b><br>This case-study features a high-speed filling line for pre-sterilized syringes. Several innovative concepts are integrated into this 50000 syringes/hour line: a spray-tunnel for the introduction of the tubs, a bale-compactor for waste, vision systems for in-process-controls, among others. The current status of the line will be discussed as well as the lessons learned thus far.  | Gerald Burkle     | Vetter            | 45         |
| 9:45       | 10:15    | Networking Break  |                   |                   | 30         |

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|-------|-------|--|--------------------------------|-----------------------|----|
| 10:15 | 11:00 | <b>Case Study – Isolated, High Speed Syringe Filling Line</b><br>This presentation addresses overall facility design of the Novartis FCC Facility in Holly Springs, NC. The facility includes a high speed syringe filling line and the presentation covers the procurement, installation, startup, commissioning and qualification of the filling and packaging line.   | Jerrod Shook                   | Novartis              | 45 |
| 11:00 | 11:45 | <b>Dividella Packaging Lines</b>   | Ernie Bancroft                 | Dividella             | 45 |
| 11:45 | 12:00 | <b>Discussion and Q&amp;A</b>  | Jerrod Shook<br>Ernie Bancroft | Novartis<br>Dividella | 15 |
| 11:45 | 13:00 | Lunch  |                                |                       | 75 |
| 13:00 | 13:45 | <b>Experiences in Filling Challenging Product Formulations in Prefilled Syringes</b><br><b>This will present AMRI's</b> experiences working with a wide array of applications and customers in clinical development, particularly challenges such as like highly viscous products, suspensions, and so on.   | Rob Worsham                    | AMRI                  | 45 |
| 13:45 | 14:30 | <b>New Developments for Drug Delivery Systems Answering to Specific Biotech Requirements</b><br>This presentation will show how BD has integrated new regulatory and GMP requirements through drug delivery systems based on new process and product. It will address issues of operational excellence aiming to lower total cost while meeting the challenges of combination product integration. The focus will be on new components including sensitive biologic drugs and a self-injection device for which current product specifications need to be redefined. | Patrick Bedgley                | BD Medical            | 45 |
| 14:30 | 15:00 | Networking Break   |                                |                       | 30 |
| 15:00 | 15:45 | <b>Pre-Filled Syringe Case Study</b>   | Ryan Hawkins                   | Cook                  | 45 |
| 15:45 | 16:00 | <b>Questions and Answers</b>   | Joerg                          | Vetter                |    |
| 16:00 | 16:00 | Seminar Adjourns   |                                |                       | 0  |