

# Virtual FAT

CASE STUDY WITH LESSONS LEARNED  
FROM THE USER AND SUPPLIER

**TUESDAY, JULY 28, 2020**  
**NOON - 1:00PM**

RSVP: <http://www.atdevents.net/register.php>

## Speakers



**Frank Haerterich** is the Sales, Project and Key Account Manager – Team Leader at Bausch + Stroebel. His career began in 1997 at Bausch + Stroebel in Germany as an apprentice in industrial management.



**Maritza López González** has been working at Amgen since 2003. She is currently, Sr Project Manager for Capital Projects at Amgen Thousand Oaks leading the drug product portfolio, including the introduction of the new Vial Filling Line for ATO Building 20.



**David Liu-Barba, PE** is a Principal Engineer at Amgen in Thousand Oaks, CA. During his nine year tenure with Amgen, he has worked with design, process, CQL and validation contractors, procured equipment including novel single-use skids, bioreactors and mixers.

*Complimentary Webinar for ISPE Members and Non-Members*

## **Virtual FAT**

### **Case study with Lessons Learned from the User and Supplier**

**Tuesday, July 28, 2020**  
**Noon – 1:00PM**

**Format:**

**GoToWebinar**

Instructions to join will be emailed one day prior

**Program Manager:**

**Merritt Postma, Director, Western Region, SKAN**

**Speakers:**

**Frank Haerterich, Sales, Project and Key Account Manager – Team Leader, Bausch + Stroebel**

**David Liu-Barba, PE, Principal Engineer, Amgen**

**Maritza López González, Sr Project Manager for Capital Projects, Amgen Thousand Oaks**

**Key Learning Objectives:**

- **Reasons for remote FAT**
- **FATs without customers attendance in the past**
- **Preparation and planning**
- **Pre-conditions for a successful remote FAT**
- **Available systems and options**
- **Expectation from the vendor**
- **Challenges**
- **Future FATs after COVID-19**

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#### About the Speakers



**Frank Haerterich** is the Sales, Project and Key Account Manager – Team Leader at Bausch + Stroebel. His career began in 1997 at Bausch + Stroebel in Germany as an apprentice in industrial management. After his apprenticeship, he accepted a position with the company in technical after sales service for Europe and Asia.

While completing a year in civil service, he received his bachelors degree for Professional of Technical Management (CCI) study as well as becoming a certified apprenticeship trainer.

His experience includes a position as Key Account Manager for a biotech company, where he was responsible for sales and project management in Brasil and Italy. He also lead a team of sales and project managers for Latin America, Italy and Spain.

After 18 years actively being part of the pharmaceutical packaging world, 2020 was the first experience with a remote FAT for a complete filling line.



**David Liu-Barba, PE** is a Principal Engineer at Amgen in Thousand Oaks, CA. He is currently working with the Drug Product Plant Engineering group as the C&Q lead for the new Vial Filling Line project for Building 20. During his nine year tenure with Amgen, he has worked with design, process, CQL and validation contractors, procured equipment including novel single-use skids, bioreactors and mixers. He has conducted FATs and has worked to improve operations in numerous projects.

He previously worked for Johnson & Johnson and NEC Electronics America as a Senior Engineer. David has his MS in Biomedical Engineering from UC Davis, where he was part of the ISPE Student Chapter. He also has a BS in Mechanical Engineering from UCLA where he was part of the ASME group. He has been an ISPE Member since 2005.



**Maritza López González** has been working at Amgen since 2003. Until last year, she was working at Amgen's manufacturing facility in Juncos, Puerto Rico. She began her career as a QC Associate in the Biochemistry Laboratory, then gained a wealth of knowledge as a Training Specialist before moving into Operations as a Project Manager for plant start-up, formulation and filling.

She is currently, Sr Project Manager for Capital Projects at Amgen in Thousand Oaks, CA, leading the drug product portfolio, including the introduction of the new Vial Filling Line for ATO Building 20.

Maritza is an EMT who received her BS in Cell and Molecular Biology from Universidad Metropolitana (UMET) in Cupey, PR and her MBA from Universidad Del Turabo in Caguas, PR.



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## REGISTRATION INSTRUCTIONS

### To Register and Receive an immediate receipt, follow these instructions:

- 1) Click on the link below then log on using your username and password: <http://www.atdevents.net/register.php>
- 2) Click on the appropriate event. Here is where you can download the event flyer also.
- 3) Scroll through the list of registration options and find the one that applies to you.
- 4) Select the payment option of your choice and follow instructions to pay. Make sure to go through all of the steps until payment is confirmed. Since our site has to go to the merchant account site, there are a couple extra clicks involved.

**ISPE California Chapter Members:** If you are an ISPE Member in California, please do not set up a new account, as you should already be in our system (takes a few days after joining). You will need your username and password to log on.

**How To Find Your ISPE Member Number or Update Your Account to a Member Account:** To update your existing account to a Member account, or to add your new ISPE Member account to our website, please forward your confirmation email from ISPE or your ISPE Membership information to Rob Fleming ([rob.fleming@yahoo.com](mailto:rob.fleming@yahoo.com)). We need your Chapter name, your ISPE Member number and expiration date. To retrieve this information, log onto the ISPE website. Click on "Account" on the top right side, then "My Account". Your Membership information (not including your chapter affiliation) is on the left side. Please take a screen shot or make a pdf of the page, then email it along with the name of your chapter to Rob Fleming to update your profile on the atdevents.net site.

**ISPE Members of Other Chapters:** You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below then follow the instructions to update your account to a member account (see above).

**Non Members:** If you do not have an account, you can set one up on the site using letters (not numbers) as your username.

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Email [Rob.Fleming@yahoo.com](mailto:Rob.Fleming@yahoo.com) for Help with Online Registration, To Set up an account or Reset password