

# HOT TOPICS IN ENVIRONMENTAL CONTROL & HVAC FOR LIFE SCIENCES

*A 3-Part Series*

Dates: 1/26/21, 2/2/21, 2/9/21

Time: 12 noon - 1:30 pm

Format: GoToWebinar

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

This 3 part webinar series focuses on understanding how use HVAC and facility design tools to assure Environmental Control and meet cGMP expectations.

- Webinar 1: Environmental Control for cGMP
- Webinar 2: Control of Special Environments
- Webinar 3: Operational Excellence

## Program Managers

- Nick Haycocks, Amgen
- Paul Crissman, Principal, Biotechnical Solutionsn

## Moderator

- Justin Cantor, Chief Strategy Officer, PSC Biotech

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**Norm Goldschmidt**  
*President*  
Genesis AEC



**Bernie Carroll, PE**  
*Director West Coast Operations*  
Genesis AEC



**Andrew Ricker, PE**  
*Sr. Mechanical Engineer*  
Genesis AEC





Three-Part Technical Series

# Hot Topics in Environmental Control & HVAC for Life Sciences

Part 1: January 26, 2021  
Part 2: February 2, 2021  
Part 3: February 9, 2021  
Noon – 1:30PM (PST)



Format:  
**GoToWebinar**

Instructions to join will be emailed one day prior

**Program Managers:** Paul Crissman, Principal, Biotechnical Solutions  
Nick Haycocks, Senior Specialist QA, Amgen

**Moderator:** Justin Cantor, Chief Strategy Officer, PSC Biotech

**Speakers:** Norm Goldschmidt, President, Genesis AEC  
Bernie Carroll, PE, Director West Coast Operations, Genesis AEC  
Andrew Ricker, PE, Sr. Mechanical Engineer, Genesis AEC

**Cost to Attend:** Free for ISPE Members  
\$35 Per Session for Non Members  
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## Overview

### Hot Topics in Environmental Control & HVAC for Life Sciences

#### Take Back to Your Job

- Be able to explain the role of HVAC to control environments and protect products.
- Understand the sources of global cGMP expectations.
- Develop and understand applicable cGMPs for Aseptic Process vs Aseptic Technique.
- Discuss HVAC system-critical parameters that must be controlled and monitored.
- Distinguish among cleanroom air classifications and understand how they are applied.
- Understand basic contamination and cross-contamination controls.
- Understand basic HVAC theory, application, monitoring, testing, and repair.

This three-part webinar series focuses on understanding how use HVAC and facility design tools to assure environmental control and meet cGMP expectations. The class will explore critical issues at each stage of the facility lifecycle, from design through CQV and operation, such as: controlling cross-contamination between products, determining the correct classification of spaces, proper control of storage temperature and humidity, setting acceptance criteria for HVAC systems and using risk assessment to set environmental criteria. The course will address common issues and problems in the operation of a facility and maintaining a state of control.

#### Part 1: January 26, 2021 - Environmental Control for CGMP

- Regulations
  - Basic Environmental Control Requirements
  - Setting Design Criteria
- Equipment - Understanding HVAC Equipment Choices
  - Filtration
  - Other Equipment
- Facility/HVAC Integration
  - Contamination Control
  - Cross-Contamination Control

#### Part 2: February 2, 2021 - Control of Special Environments

- Regulations
  - Special Environmental Control Requirements - Aseptic
  - Special Environmental Control Requirements - Biotech
  - Special Environmental Control Requirements - ATMP
  - Special Environmental Control Requirements – 503B
- Equipment
  - Pass-through Boxes
  - Environmental Monitoring Systems
- Facility/HVAC Integration
  - Classification

#### Part 3: February 9, 2021 - Operational Excellence

- Setting Alert Limits
- Cleanroom Testing
- HEPA Certification
- Airflow Visualization
- Maintenance and Calibration



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Greater Los Angeles  
Area Chapter

# Hot Topics in Environmental Control & HVAC for Life Sciences SPONSOR INVOICE

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- 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) If payment is required, 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.

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