

How to Select a CDMO

Free for Members and Non-Members

Strategies, approaches, and challenges in selecting a contract development manufacturing organization (CDMO)

Learn about the latest topics that influence the selection process including:

- Regulatory Enforcement
- Analytical Capabilities
- Schedule Availability
- Technology
- Geographic Location
- Tech Transfer Capabilities
- Project Management Capabilities
- Change Order Methodology
- Other Best Practices

DEC 1 FROM NOON - 1 PM

RSVP: [HTTP://ATDEVENTS.NET/REGISTER.PHP](http://atdevents.net/register.php)



ISPE

Greater Los Angeles
Area Chapter

RSVP: [HTTP://ATDEVENTS.NET/REGISTER.PHP](http://atdevents.net/register.php)

SPEAKERS



Benir Ruano

*VP, Global Manufacturing &
Technical Operations*
Xeris Pharmaceuticals



Steven Hager

Director, Science & Technology
Catalent Biologics



Shawn Cain

Chief Operating Officer
LSNE



Alex Konstantinidis

Director of Program Management
Pfizer

PROGRAM MANAGERS



John Clapham

Chief Executive Officer
PSC Biotech



Martha Sosa

Validation Manager
Ajinomoto Bio-Pharma Services



Justin Cantor

Chief Strategy Officer
PSC Biotech

MODERATOR



ISPE | Greater Los Angeles
Area Chapter

RSVP: [HTTP://ATDEVENTS.NET/REGISTER.PHP](http://atdevents.net/register.php)

Complimentary Webinar for ISPE Members and Non-Members

How to Select a CDMO A Two-Part Series Covering **Strategies, Approaches and Challenges In Selecting a Contract Development Manufacturing Organization (CDMO)**

Part 1: December 1, 2020 (Part 2 in January)

Format: GoToWebinar Instructions to join will be emailed one day prior

About The Speakers:

Shawn Cain is currently the Chief Operating Officer at LSNE, a pharmaceutical and medical device CDMO, acquired by Permira Funds in 2017. He has over 30 years of experience in combining process engineering and project management to direct the development and manufacture of sterile pharmaceuticals, cell-based biologics, and medical devices. Most recently he was at Organogenesis, Inc., specializing in bio-active wound healing. His past experience includes Director of Operations for Formatech, Inc., a pharmaceutical CDMO, Interim President and CEO of Arbios Systems, Becton Dickinson's Discovery Labware, Biologics Business, VP of Operations for Circe Biomedical, where he led the development of the bioartificial liver technology. Cain holds six patents and received his MS degree in Biological Sciences from the University of Massachusetts and a BS in Biological Sciences from Northeastern University.

Steven Hager, PhD, is the Director of Science and Technology for Catalent Pharma Solutions. Dr. Hager joined Catalent in 2001 and is responsible for technology and innovation support for Catalent Biologics drug substance development and manufacturing. Dr. Hager received his BA from St. Olaf College and PhD from the University of Wisconsin-Madison in physiology and biochemistry and performed postdoctoral work at the University of Illinois Medical Center, Department of Biochemistry in Chicago, IL.

Alex Konstantinidis is the Director of Program Management at Pfizer. He has a strong record in program management and extensive anti-infectives experience, mobilizing cross functional teams to execute product development, from inception to FDA submission, and effective commercial manufacturing. He has seven years CMC program management experience. He has established PM teams to manage development and launch activities and ensured effective stakeholder engagement to accomplish team goals, address conflicts, and mitigate partnership and product risks. He has 14 years of technical expertise in roles of progressively higher responsibility in leading pharmaceutical companies performing product development, technology transfer, and establishing robust manufacturing processes.

Benir Ruano is the Vice President of Global Manufacturing and Technical Operations for Xeris Pharmaceuticals. He has 37 years of experience with biotech, pharmaceutical and medical device companies working in development, engineering, clinical and commercial manufacturing/supply chain. His previous experience includes technical leadership roles at CTI Biopharma, OSI Pharmaceuticals, Pharmatech, Aradigm, Sanofi Pasteur, Bio-Rad and Eli Lilly.

Thank You To Our Annual Sponsors

PLATINUM

  **PSC Biotech**  **STAINLESS SERVICES**  **PINNACLE PROGRAM
2020 Global Sponsor**

GOLD

 **Murray Company**
MECHANICAL CONTRACTORS  **Pacific Rim Mechanical**  **DPR
CONSTRUCTION**

SILVER

 **BioPharm
Engineered Systems**
A Critical Process Systems Group Company



ISPE®

Greater Los Angeles
Area Chapter

REGISTRATION INSTRUCTIONS

Please note that our system does not email confirmations for complimentary events, however, you will receive a link to join the day before the webinar.

To Register, 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) 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.

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). 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.

ISPE Greater Los Angeles Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tax ID#95-4452996.

Email Rob.Fleming@yahoo.com for Help with Online Registration, To Set up an account or Reset password