



Connecting Pharmaceutical Knowledge

Great Lakes Chapter

Fall—Winter 2023 Newsletter

President's Message



Joe Robinson, QCXP, CPIP
CAI Regional Manager, Midwest,
ISPE GL Chapter President

Hello and welcome ISPE Great Lakes Chapter members. I hope all of you had a great summer and spent some quality time with your families. In case you missed the ISPE GAMP Forum in Indianapolis on June 15th, we are planning to have this event again in November 2nd in the Chicagoland area. Don't miss out on a great event and the opportunity to learn from industry experts and network with colleagues. Information will be out soon on registering for the event.

Student Chapters are the future of our industry. The Chapter is engaging with several of the Student Chapters that have been around for a while as well as working to establish a few new ones. Engaging people early in their career path is a great way to attract new members and new ideas that will benefit the industry. We also are heavily engaged with the Women in Pharma at the national level. I believe there will be information on this at the event in Chicago, which is a few weeks after the Annual Meeting in Las Vegas.

If you or anyone you know are interested in joining and helping us advance the goals of the Chapter, please reach out to one of the Chapter Directors. If you have ideas for topics that would be interesting and beneficial for the Chapter membership, we want to hear from you. If you have a particular location in mind for an event, please share those with the GLC Board. We want to hear what you have to say.

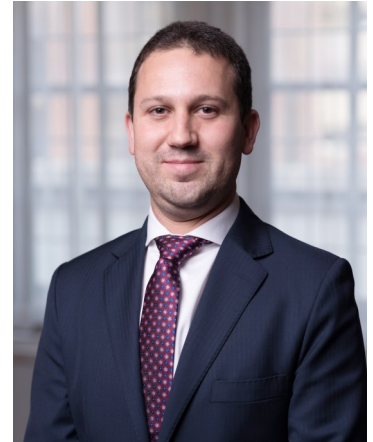
I, along with the entire GLC Board, appreciate all your contributions toward the Chapter's goals, bringing pharmaceutical engineering professionals together and providing learning opportunities for everyone. Please contact me at:

joe.robinson@cagents.com if you have something to contribute or would like to be more involved.

Member Spotlight: Andres Roman

Tell us about yourself - what are you studying in college and why do you have an interest in the pharmaceutical industry?

I'm currently pursuing a MS in Engineering Management at Purdue University. I have a mechanical engineering background (from Purdue as well) and 10+ years of project management work experience, especially within pharma. I worked at Qualipharm Laboratorio Farmaceutico, an Ecuadorian CDMO, in which I was able to execute capital projects focused on facilities expansion, equipment commissioning and start-up, for a variety of pharmaceutical forms: from liquids, emulsions, up to effervescent tablets. This experience provided me with enough understanding on how complex and challenging the pharmaceutical industry could be, but at the same time how rewarding it is to acknowledge you contribute to make people live healthier lives.



**Andres Roman —
Graduate Student**

Purdue University

Tell us what motivates you and drives your passion for your studies?

I chose pursuing graduate studies in Engineering Management because I saw a great opportunity to combine engineering and business curricula that would offer me tools to grow professionally in pharma and become a change agent within the industry. I saw that Purdue Engineering Management Program fitted my future endeavors. Purdue MEM is very versatile and allows graduate students to take ownership of their plan of study, so each course I have taken has allowed me to gain a deeper technical and business understanding. I have been able to combine my interest in strategic management and entrepreneurship with pharmaceutical engineering and systems engineering courses. Additionally, my engineering program in partnership with the Bayer Foundation permitted me to gain experience in consulting through a social innovation project. I was paired up with four talented engineering management students, and designed a go-to market strategy for an African biofertilizer manufacturer that aims to maximize crop value at affordable costs. It is gratifying to look back in time and acknowledge that this project in particular will make an impact in the lives of Tanzanian farmers and counteract food scarcity in such region.

Tell me how long you've been a member of ISPE and what you've gained from ISPE and chapter membership? Also, tell us more about what you are hoping to achieve as the president of Purdue student chapter?

Purdue ISPE chapter was reinstated at the beginning of 2023, and since then I have been part of the organization. In the spring, I had the chance to be elected as the VP and worked closely to Anelis Chiluisa, our former president. I am the vivid example that good things happen when you become an active member of ISPE. Thanks to one of our company chats last semester, I had the chance to connect with the president of the pharmaceutical consulting firm I am currently doing a co-op. During this academic year, we are trying to build a bridge between our students and the industry, organizing free workshops and events that will not only enhance networking opportunities but also will allow our members to gain knowledge in pharmaceutical topics that are not usually taught at school, such as cGMPs or Process Validation. To do this, we are inviting subject matter experts through personal contacts and the ISPE network. This will be our key focus to recruit students and retain memberships. We aim to increase our total enrollment by 70% and have at least 35% of our members to be active participants.

Is there something you'd still like to accomplish professionally or personally with the Chapter that our readers can help you with?

I would like students to identify Purdue ISPE as a key partner to their professional development. Likewise, while our community is exposed to industrial networking and our lectures, we will provide a unique set up for companies' branding. I foresee that our workshops could potentially save training and inductions costs for companies, as we will be preparing our students to be the pharmaceutical industry workforce. I would like our readers to reach out to me with topics they believe would be beneficial for our members to learn and help us out co-organizing and co-sponsoring them.

- Give me a little personal info – what you like to do outside of studies, family, where you grew up, etc.

I was born and raised in Quito-Ecuador. This is the second time I am living permanently in the US. I am married to Maria Isabel, she is an Ecuadorian MD, so we can say that healthcare interest runs in the family. We both have a 2-year-old baby (Matias), and a 3-year-old- English Bulldog (Lucas), and most of my free time I like to spend it with them. Raising up a family while studying and working as co-op student has been a joyful adventure. I also like to watch Ecuadorian and European soccer. I root for Liga de Quito and Real Madrid, respectively.

2023 Great Lake Chapter Board of Directors:

Officers

President - Joe Robinson, CAI, Regional Manager, Midwest

Vice President - Jordan Rhoades, Jacobs, Process Engineer

Treasurer - Sara Brothers, Jacobs, Senior Project Manager

Secretary - Chris Timmerman, CAI, Project Manager / Validation Engineer

Past President - Aaron Mertens, Steris, Technical Services Manager

Board Members

Board Member - Rick Corbett, Rayzebio, Sr. Director-Operations & Engineering

Board Member - Brad Henry, Performance Validation, Vice President

Board Member - Allen Koester, PCI (A SalasOBrien Company), Sr. Project Manager II

Board Member - David Simoens, cGMP Consulting, Inc., COO.

Board Member - Lance Lafler, Aldevron, Sr. Validation Engineer

Board Member - David Goodlander, CAI Client Manager

Board Member - Keith Dodson, Cambrex, Director of Commercial Sales, Drug Product

Board Member - Dave MaAlonan, DWM Management Consulting Inc. Project Mgmt. Consultant

Board Member - Steven Shull, LBR Regulatory, Quality Assurance Manager

Student Chapter Liaison - Ben Balster, Plus Group, Associate Process Engineer

Emerging Leaders Chair - Carolina Serrano –Eli Lilly & Company, Operations Improvement Engineer

ISPE GLC Welcomes New Members

The Great Lakes Chapter consists of members in the states of Michigan, Wisconsin, Illinois, Indiana, Ohio, and Kentucky. The Great Lakes Chapter of ISPE welcomes 19 new members in Apr 2023– May 2023. Please welcome them to the organization and the pharmaceutical industry.

Matthew Hayden, Trident Automation, Inc., Kimberly ,WI

Brian Minick , Fishers ,IN

Anna Bandecca, Evonik Corporation, Lafayette ,IN

Charletha Cade, Barry-Wehmiller Design Group, Lansing ,IL

David Hopper, Eli Lilly, Indianapolis ,IN

Cole Brunson, Flad Architects, Madison ,WI

James Burkholder, ABB, Cleveland ,OH

Steve Miller, University of Michigan, Birmingham ,MI

Vaughn Lubarski , Warsaw ,IN

Brian Salbilla, Azzur Group, Lake Forest ,IL

Elan Winterberger, Perrigo Company Plc, Grand Rapids ,MI

KRISTIAN MILEC , LASALLE ,ON

Marjeta Gjakaj, Optima Machinery Corp-Pharma Div, Green Bay ,WI

Danik Alexander-Renaud, Laporte Consultants, Chicago ,IL

Casey Chamberlain, Rees Scientific, Blue Mounds ,WI

Grant Selking, Thermo Systems, Carmel ,IN

Kenneth Smith, , Bloomfield ,IN

Upcoming Conferences 2023



GAMP Forum
When: November 2, 2023
Where: Hilton Chicago / Northbrook
Register: <https://ispe.com/2023gamp>
FDA Invited

Speakers:
AI & ML: Brand Stockton (Co-Founder, The Triality Group), Eric Starb (Head of Quality, Validated Cloud)
Critical Thinking: Stephen Ferrell (VP IT Governance & Software Assurance, Compliance Path)
Infrastructure: Michael Martore (Director, Quality Systems, Abbott)
Distributed Ledger: Tanya Sharma (Co-Founder, Assurance)
CSA: Khalid Mousally (VP Clients & Regulatory Affairs, Compliance Group)
ISPE Great Lakes Chapter

Sponsored by: KPMG, PricewaterhouseCoopers, ProcellaFX, G&L, Quality Co.

[ISPE GLC GAMP Forum](#)

2 November 2023
Greater Chicagoland Area, IL US



2023 ISPE
Annual Meeting & Expo

[2023 ISPE Annual Meeting & Expo](#)

15 - 18 October 2023
Las Vegas, NV USA and Virtual



2023 ISPE
Pharma 4.0™ and Annex 1 Conference

[2023 ISPE Pharma 4.0 & Annex 1 Conference](#)

11 - 12 December 2023
Barcelona, Spain and Virtual

On Demand Conferences



[ISPE Best of Pharma Series](#)

Access the most premier presentations offering compelling insights, strategies, and best practices from experts representing global health authorities and leading pharma organizations.

Volunteer Opportunities

Would you like to get involved with other professionals in the Pharmaceutical industry? Do you have a special skill or passion? Would you like to see new or different events to help you in your career? The Great Lakes Chapter of ISPE is looking for volunteers to help with organization of events in your area. If you are interested, reach out to the board members listed .

Technical Articles Wanted:

Do you have a technical discovery or best practices that you would like to share with the Pharmaceutical Industry? This is a great way to get recognized by your peers for the great work that you do every day. We are looking for technical articles for the Great Lakes Quarterly Newsletter>

If you have something you would like to contribute, please send to Joe Robinson, joe.robinson@cagents.com or Allen Koester, allen.koester@salasobrien.com.

Linked In Visit the Great Lakes Chapter Linked-In Page at:

<https://www.linkedin.com/company/ispe-great-lakes-chapter/>

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Interested in sponsoring the ISPE Great Lakes Chapter? Check out our new sponsorship strategy!

Sponsorships	Cost	Benefits
Newsletter Advertising		
1/2 Page	\$125/issue or \$400/year	Advertisement in each newsletter (4 issues per year)
1 Page	\$175/issue or \$600/year	
Webpage Advertising		
https://ispe.org/great-lakes-chapter	\$275/6 months or \$550/year	Logo on banner at bottom of ISPE.org page. GLC LinkedIn page will share requested company content ¹
Single Event Sponsorships		
Platinum	To be determined per event basis.	
Gold		
Silver		
Webinar (1 hour)	\$250	Company logo on slide deck and webinar advertising
Chapter Sponsor		
Number of chapter sponsorships limited to 6 companies	\$1500/year	1/2 page newsletter advertising and website advertising for year
		Silver level event sponsorship for every event ISPE Great Lakes chapter hosts ²

¹Content to be shared on LinkedIn must be approved by member of GLC board. Limited to post per month. Post will start with *SPONSORED CONTENT*.

²If sponsorship company wants to be a Gold or Platinum level sponsor, an additional \$200 or \$400 will be required per event to move from silver to gold or Platinum. Number of events held is not guaranteed and may change year to year.

Please contact Sara Brothers and Joe Robinson to set up your sponsorship!

Sara.Brothers@jacobs.com
Joe.Robinson@cagents.com

Membership/ Become a member and grow with us!

Discover the advantages of an ISPE Membership for every stage of your career. Whether you are new to the pharmaceutical industry or a seasoned professional, ISPE is your Society of Choice

Networking Opportunities

Whether networking at face-to-face events or collaborating online, the value of ISPE is in the links forged between industry professionals with common work challenges, connecting professionals and companies to practical guidance and dialogue between industry and global regulators.

Membership Directory: Connect with 18,000+ other Members from nearly 90 countries around the world with the Membership Directory.

CoP Online Discussion Forums: Ask questions, find solutions to common problems and share your industry knowledge and expertise with colleagues from around the world.

Affiliates and Chapters: Attend events, collaborate and share best practices in your local geographic region and language.

Networking Events: Interact with fellow industry colleagues at a wide variety of face-to-face networking events at global ISPE conferences and the ISPE Annual Meeting.

Technical Resources

Guidance Documents, industry-leading publications, and on-demand training courses and webinars provide practical information and solutions to real-world problems.

Guidance Documents: Get special savings as an ISPE Member on industry Guides that provide the collective knowledge of leading thinkers on manufacturing best practices, regulatory compliance and international trends and best practices.

Pharmaceutical Engineering Magazine: Your complimentary subscription to Pharmaceutical Engineering magazine gives you access to valuable information on the latest scientific and technical developments, regulatory initiatives and innovative solutions to real-life problems and challenges.

Review and Comment on Regulatory Guidance: Pharmaceutical professionals at all stages of their careers turn to ISPE for the latest regulatory information. Help shape your industry by providing input into ISPE's official industry response to draft guidance from regulatory agencies around the world.

Professional Development

Industry-leading education and training, global volunteer opportunities and industry-focused career solutions allow ISPE Members to grow their professional knowledge and skills.

Education and Training: Save on a variety of education and training programs, including ISPE global conferences, onsite training delivered at your company, online webinars and courses, and professional development and networking events conducted through your local Affiliate or Chapter.

Volunteer Opportunities: Volunteer with ISPE to gain professional experience and recognition in the industry. ISPE Volunteers experience the personal benefits of volunteering while having the opportunity to make a difference and influence the industry we serve. Learn more

Career Solutions: Get noticed by the right people in our industry. Post your resume or job opportunity today to be seen by employers and job seekers specializing in the pharmaceutical and biotechnology industries.