

The In's and Out's of Innovation Webinar Series

Presented By:



Session 4:

Working with Regulatory Agencies

Tuesday, April 12, 2022
10:00 am - 11:00 am CST

Overview:

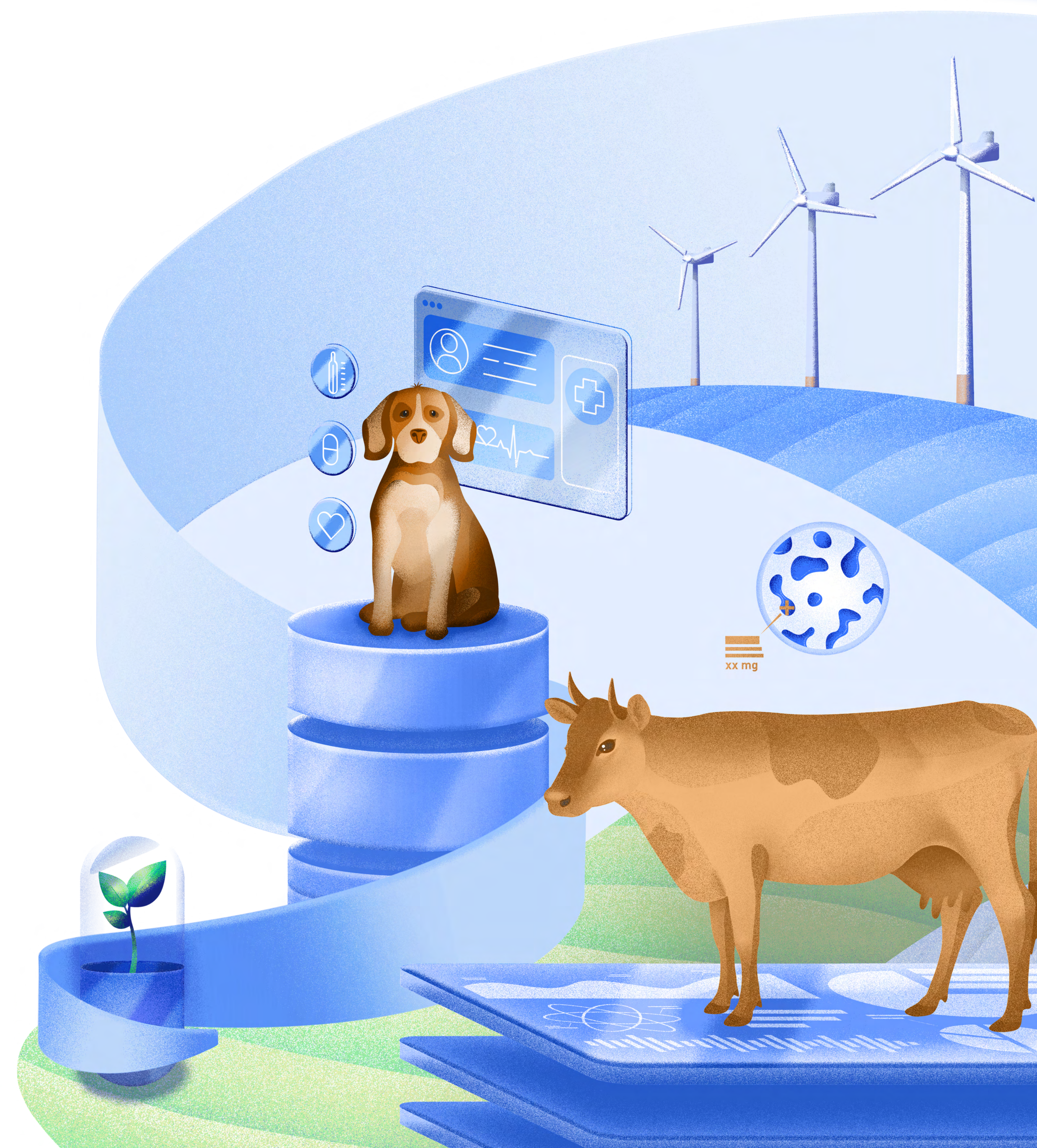
Please join us at the fourth session of *The In's and Out's of Innovation Series*.

You will learn about working with the FDA and other agencies for domestic and international sale.

We will work to make sure you understand key regulations for new life sciences, human health and animal health companies, different regulatory submissions and regional requirements.

This event is presented by Plug and Play Tech Center with collaboration with Go Topeka and Washburn University Small Business Development Center.

Register below.



FOR MORE INFORMATION

l.lebahn@pnptc.com

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Presented By:



Meet the Speakers from:



Meseret Jimale

Located in Toronto, Meseret Jimale is the Director Of Technical Operations for PSC Biotech in Canada. Her over 30 years' experience working in the biotechnology industry includes Business Development, Quality Assurance, Quality System, Regulatory Compliance, Strategy, and Quality Auditing. She executes domestic and international suppliers' audits to ensure compliance with cGMP/GLP/ICH/FDA/EU requirements and quality agreements, leads international regulatory assessment activities, and leads quality oversight activities for startup pharma companies. Meseret has a Master's degree focused in Organic Chemistry from University of Regina.

Brandon Clough

Brandon Clough is the Chief Revenue Officer at PSC Biotech. His management experience in Production and Quality for FDA Regulated industries includes over 25 successful regulatory inspections and background in working with DMF's, CEP's, NDA's, etc.. In addition, he has strong experience in leading teams through strategic planning, profit maximization, supplier supply chain management, and acquisitions. He is a Kaizen and 5S teacher/implementation leader.

Akshaya Mohan

Akshaya Mohan is currently working in the Regulatory Affairs division at PSC Biotech Corporation. She has over 3 years of consulting experience for pharmaceutical, biological, veterinary and other regulated products with multinational companies like Pfizer, AbbVie, and technical experience with companies such as GlaxoSmithKline Pharmaceuticals (GSK Rx India). She has been involved in developing various quality control procedures and regulatory consulting to adhere to corporate policies. Prior to that, she was part of the team responsible for launching new drug product in the market.

She currently holds Dual master's degree , Masters in Business Administration (MBA) from University of Central Florida as well as Masters in Pharmacy with specialization in Pharmaceutical Sciences from NMIMS, India .

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