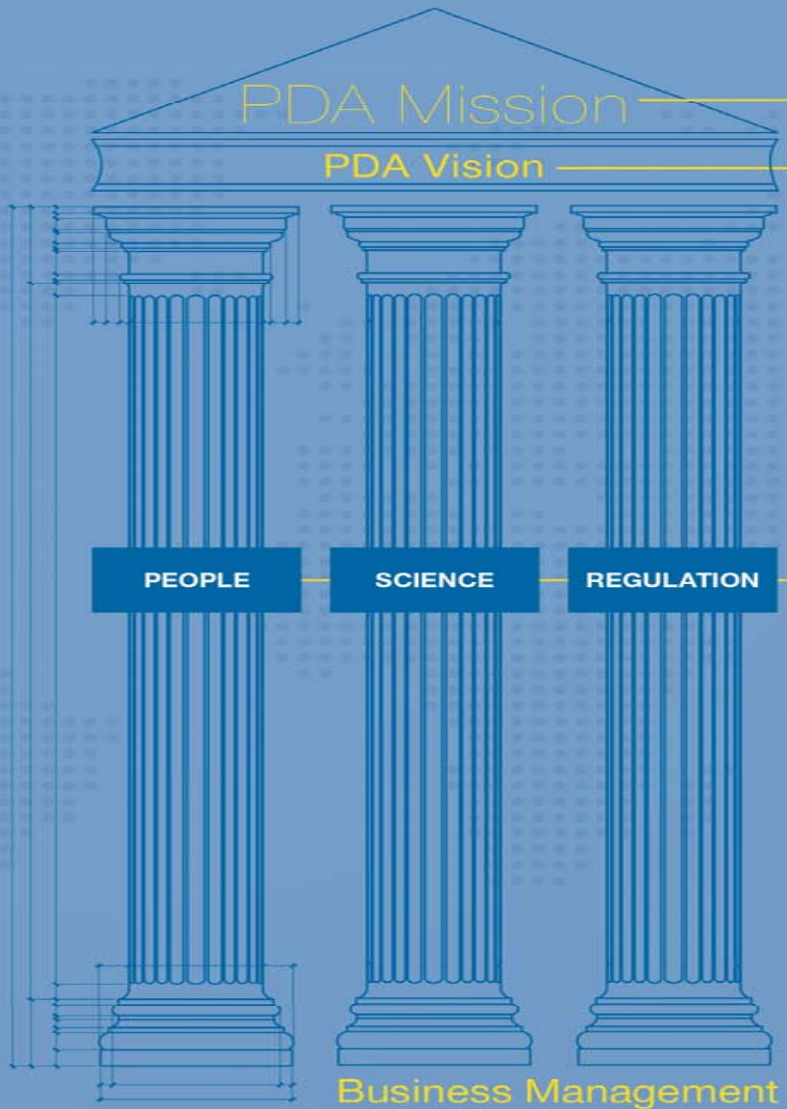
Data Integrity & Quality Culture

What is PDA?

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.



MISSION
To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

VISION
To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community

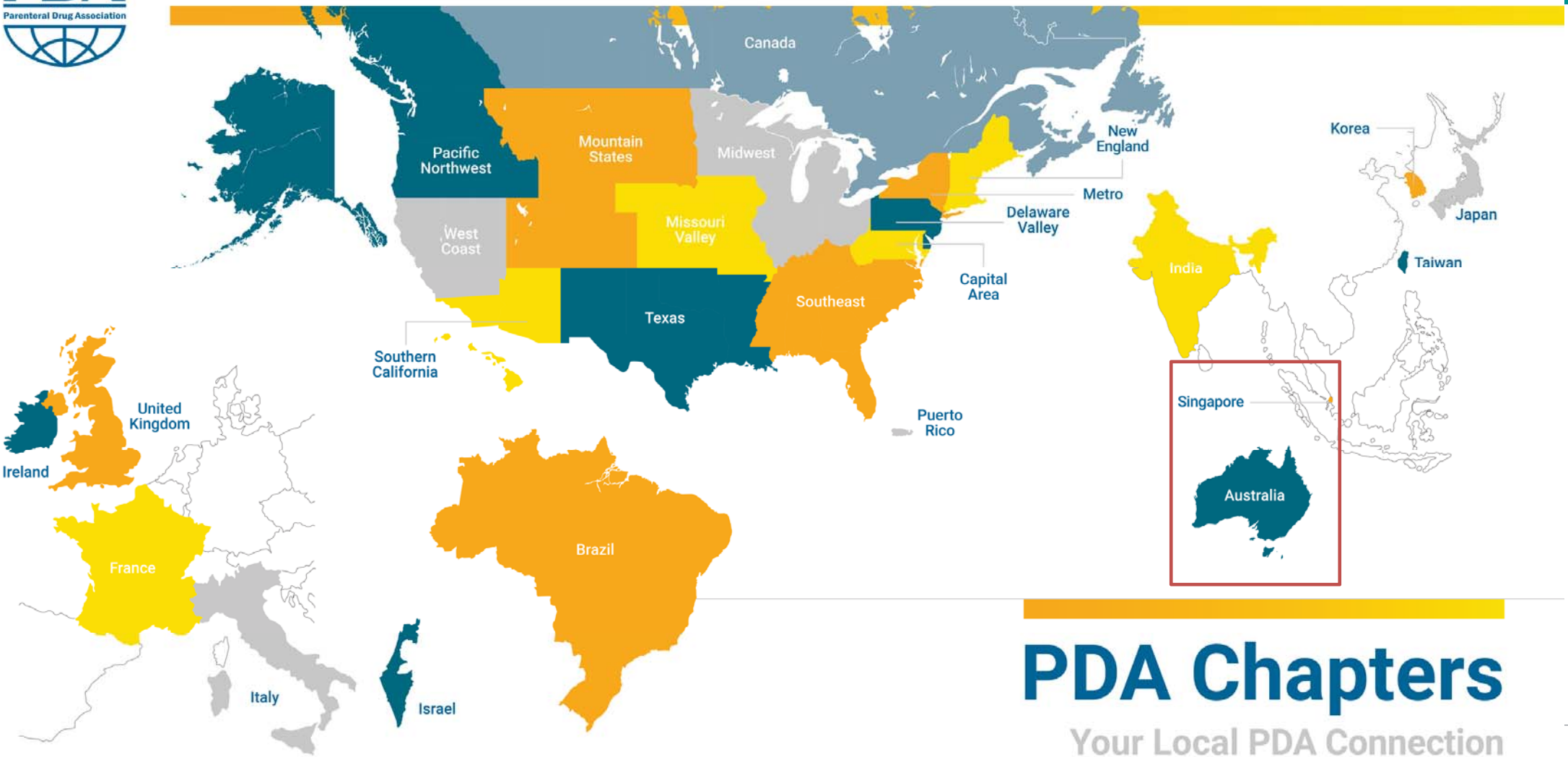
PDA: Connecting People, Science and Regulation®

PEOPLE: Enhance the value of PDA membership

SCIENCE: Be recognized as a leading organization for manufacturing science, quality and innovation

REGULATION: Our regulatory activities are scientifically and technically focused, and current information is communicated to our members

BUSINESS MANAGEMENT: Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies


PDA
Parenteral Drug Association
Canada
Pacific Northwest
Mountain States
Midwest
New England
Metro
Delaware Valley
Capital Area
Missouri Valley
West Coast
Texas
Southeast
Southern California
Puerto Rico
India
Korea
Japan
Taiwan
Singapore
Australia
United Kingdom
Ireland
France
Italy
Israel
Brazil
PDA Chapters
Your Local PDA Connection

Where are you joining us from today?

- 800+ registrants for todays symposium
- 40% of registrants from our key PDA Chapter areas; Singapore & Australia
- 85% of registrants from other parts of Asia Pacific

Member Benefits Summary

View the full library of **Technical Resources** in our online TR Portal for free!

Network with regulators and industry experts through PDA events and volunteer opportunities

Read the latest **research** on the *PDA Journal of Pharmaceutical Science and Technology* website

Catch up on industry and Association news with the *PDA Letter*

Grow **your local network** and learn about issues affecting your region through chapter involvement

Gain access to **professional resources** like our Online Membership Directory and PDA Career Center

Take advantage of **discounts** on conferences, courses and books

PDA Technical Report Portal

PDA Members have 24/7 access to more than 70 active technical resources in the PDA TR Portal.

Now Available! 2020 PDA Bookstore Catalog

Explore PDA's full library of publications, including the technical reports, books and much more!

For more information on all PDA's expert bio/pharmaceutical publications and resources for the pharmaceutical manufacturing industry, please visit pda.org/bookstore.

Member Types and Pricing

Regulator/Health Authority	Retired/Unemployed	Student	Emerging Economy/Academic	Young Professional	Standard/Individual
$0-12 per year, USD.	$25 per year, USD.	$30 per year, USD.	$100 per year, USD.	$100 per year, USD.	$279 per year, USD.
PDA Member Discount	PDA Member Discount	PDA Member Discount	PDA Member Discount	PDA Member Discount	PDA Member Discount
PDA Member Directory	PDA Member Directory	PDA Member Directory	PDA Member Directory	PDA Member Directory	PDA Member Directory
PDA Letter (electronic)	PDA Letter (electronic)	PDA Letter (electronic)	PDA Letter (electronic)	PDA Letter (electronic)	PDA Letter (electronic)
PDA Journal (electronic)	PDA Journal (electronic)	PDA Journal (electronic)	PDA Journal (electronic)	PDA Journal (electronic)	PDA Journal (electronic)
PDA Technical Report Portal (electronic)	PDA Technical Report Portal (electronic)	PDA Technical Report Portal (electronic)	PDA Technical Report Portal (electronic)	PDA Technical Report Portal (electronic)	PDA Technical Report Portal (electronic
Download New TRs (electronic)				Download New TRs (electronic)	Download New TRs (electronic)
					PDA Letter (hard copy)

https://store.pda.org/JoinPDA.aspx

Agenda

Time	Presentation	Speaker
08:10 – 08:55 hrs (Singapore) 10:10 – 10:55 hrs (Australia)	Data Integrity – Focus on Microbiological Testing Challenges	Bruce Loxley
09:00 – 09:45 hrs (Singapore) 11:00 – 11:45 hrs (Australia)	Data Integrity – Focus on Quality Culture	Wallace Torres
09:50 – 10:35 hrs (Singapore) 11:50 – 12:35 hrs (Australia)	Data Integrity – will the Cloud Reign?	Paul Kerr
10:40 – 11:00 hrs(Singapore) 12:40 – 13:00 hrs(Australia)	Question Time	All Speakers

Bruce Loxley

- Bruce performs regional and global auditing of GSK Vaccines and third party provider sites and functions focusing on AsiaPac. Bruce has 29 years in the Pharma and Vaccines businesses, variety of roles in Validation and Compliance in both Drug Substance and Drug Product Manufacturing in UK, France and Singapore.
- Bruce has been a PDA Singapore Chapter member since 2014. Since February 2020 he has been PDA Singapore Chapter President
- Bruce holds a Bachelor in Applied Science (Applied Chemistry) from Curtin University of Technology, Perth, Australia

Wallace Torres

- Wallace I. Torres is responsible for all the Quality units that provide support to the Manufacturing operations on a Single Use Systems (SUS) plant. Prior to Singapore, he was the Quality Executive Director for the Drug Products manufacturing facilities in Puerto Rico.
- Prior to Amgen, Wallace worked for 25 years at Hoffmann La Roche in several positions in the QC/QA, Manufacturing, Strategy, and Supply Chain areas. His experience includes responsibilities as Site Head of Manufacture, Global Head of Risk Management, Global Quality Manager and QA/QC Head at Contract Manufacturing facilities. During the years he also held several leadership positions in Switzerland, USA, Mexico and Brazil.
- He holds a B.S. degree from the University of Puerto Rico (Biology), an MBA from the University of Phoenix (Management), an MBA in Advance Management Practices from the University of South Australia and a Doctorate on International Business Management (PhD) from the Swiss Business School.

Paul Kerr

- Paul has over 35 years broad pharmaceutical experience across various technological areas (Laboratory, Manufacturing and IT) as a qualified chemist, an IT project manager and consultant. He has conducted IT gap analysis and compliance audits for companies to a range of international standards and regulations, including FDA CFRs, PIC/S, EU and ISO/IEC. Paul trains in computer validation (21 CFR Part 11 and GAMP) and assists companies establish IT Governance compliance and computer validation programs. He regularly gets involved with specific validation projects using automated systems, on premise and in the cloud, in clinical, manufacturing, laboratory and QMS environments.

Question Time

Can Bruce share examples of systems that he might come across in companies that encourage and promote speaking up about DI?

Question Time

Wallace - How do we identify and reward positive DI behaviour, especially since it is supposed to be the default behaviour?

Question Time

Wallace - How do you get the shop floor personnel to embrace DI culture?

Question Time

Bruce - In case of DI violation investigation: At which stage of investigation person involved in violation should be isolated (prohibited for further routine work)?

Question Time

Bruce - Is joint microbiological analysis by internal / external auditor is helpful to know DI issue in Laboratory ?

Question Time

Wallace - Is it possible to measure data integrity and quality culture in Quality Metrics? Can you share your experience on this?

Question Time

Bruce - What data needs to have both performer and Verifier signature. How to do you know which data should have both Performer and Verifier?

Question Time

- Paul - Are there specific guidelines on how to validate Cloud technologies? Will this follow the GAMP5?

Question Time

- Paul - You presented SaaS provider validation leverage follow V Model. Recently I was aware about Computer System Assurance (CSA Concept). How do you see the CSA Concept fits to V-Model moving forward?

Question Time

- Paul - What sort of issues in Data Integrity do you expect to see as a result of this COVID-19 pandemic, say either directly or indirectly?

PDA Resources for Developing a Mature Quality Culture

http://www.pda.org/scientific-and-regulatory-affairs/quality-culture

Thankyou for joining us today

- Thank you PDA Singapore and Australia Chapter Committee Members
- Membership discount codes and slides from todays presentations will be shared with attendees via e-mail in the coming days

PDA
Parenteral Drug Association

pda.org/2020atmps

2020 PDA Advanced Therapy Medicinal Products Month Webinar Series

WHEN: 11:00 a.m. ET every Tuesday and Thursday in June

WHERE: From the convenience of your own computer or mobile device.

WHAT: A series of nine webinars featuring industry and regulatory experts. Each webinar includes ample opportunity for a live Q&A with the presenters.

COST: $200 for each individual webinar. Make the most of available discounts when you register as a team of 10 or more or if you register yourself for all nine webinars!

CONNECTING PEOPLE SCIENCE AND REGULATION®

#PDAatmps

2020 PDA Asia Pacific

Pharmaceutical Manufacturing & Quality

The emerging regulatory trends and their impact

22-23rd Sep. | Grand Copthorne Waterfront Hotel | Singapore

Andiyanto Satandar, PhD
Manager Life Sciences, HGP Asia

Bruce Loxley, Program Chair
Snr. Mng. Internal Audit, GSK

Emily Cheah, PhD
M.D., Charles River Laboratories

Ratna Solsialin
Quality Head, Kalbio Global Medika

Georg Roessling, PhD
Snr. Consultant Asia, PDA

MEETING OVERVIEW

The conference will give an update on the emerging GMP and compliance regulations and their impact on pharmaceutical manufacturing and quality functions. The program will include an overview of the upcoming changes and how those changes will impact your requirements in a pharmaceutical environment. An important part of the Conference is dedicated to their implementation of risk-based approaches in manufacturing.

CONFERENCE HIGHIGHTS

Control Strategy, as part of the quality system
Manual Aseptic Processing to Modern Fill Finish Operations
Aseptic Process Simulation
Data Integrity and Challenges for Quality Control Labs
Microbiology for Sterile and Non-Sterile Manufacturing

SPEAKER HIGHLIGHTS

Maik Jornitz, G-CON
Ricoh Schulze, EU, Inspector in Germany
Dinesh Khokal, Amgen, former HSA regulator
Goh Choon Wee, Roche
Andy Hopkins, former MHRA and rapporteur of Annex 1
Gabriele Gori, GSK
Stephan Roenninger, Amgen

REGISTRATION

Registration Fees	
Members	$USD699
Non-members	$USD799
Government and Young Professionals	$USD399

Speaking Opportunities
Georg Roessling, PhD
Email: roessling@pda.org

Exhibition/Sponsorship Inquiries
Tony Chan
Email: chan@pda.org

Registration Inquiries
Email: asia-pacific@pda.org

For registration information visit www.pda-asiapacific.eventbank.com/event/19462

Grand Copthorne Riverside Hotel
392 Havelock Road, Singapore, 169663 | Phone: +65-6733 0880

**Disclaimer: Depending on the ease of border restrictions, this event will be conducted F2F and/or Virtually*