CONFERENCE PIC/S AND GMP ANVISA CP 653/19

PDA Parenteral Drug Association
BRAZIL CHAPTER

JULY 22-24, 2019 - SAO PAULO

July 22

Dinesh Khokal, Amgen, PDA Singapore

- PIC/S Introduction
- Pharmaceutical Quality System
- Personnel
- Documentation
- Production
- Quality Control
- Complaints and Product Recall

July 23

Dinesh Khokal, Amgen, PDA Singapore

- Manufacture of sterile medicinal products
- Sampling of starting and packaging materials
- Qualification and validation
- Reference and retention samples
- Quality risk management
- How to be prepared for PICS Audit
- Data Integrity

July 24

Ronaldo Gomes – Inspection Manager – ANVISA

- Top Doubts
- Implementation schedule
- PDA Proposal
- Questions and Answers
- Round Table

Sponsor KAYE

Partner AMGEN

PLANNING TEAM

If you have any question, feel free to contact the PDA staff by e-mail picsqa@pdabrazil.org.

Quality System	Tathiane Castro
People	Vitorio Santos
Documentation	Maria Amaral
Production	Alexandre Terada
Quality Control	Vitorio Santos
Complaints and Product Recall	Vinicius Paccola
Sterile Manufacturing	Alexandre Terada
	Rose Nascimento
Sampling of Starting and packaging materials	Tathiane Castro
Reference and Retention Samples	Luiz Wenzel
Quality Risk management	Jaqueline Novais
Data Integrity	Leonidas Orjuela
Biological products	Wolfgang Harry
Experimental products	Tatiana Oliveira

CONTACT AND INFORMATION

11-2894-9730/31 - pics@pdabrazil.org
8:00 às 17:00

Price 3 days:
PDA Member: R$ 1.000,00
Non Member: R$ 1200,00

Price day 24
PDA Member: Without cost
Non Member: R$ 400,00

Espaço Fit Eventos
Chácara Santo Antônio - Rua Paul Valéry, 255A - ,SP

Dinesh Khokal, Amgen, PDA Singapore

Dinesh is currently responsible for supporting Amgen's outward facing efforts to collaborate effectively with industry PEERS and regulators to engage, understand, translate and deliver impact in the evolving external GxP landscape.

Prior to Amgen, Dinesh held the role of Director, Therapeutic Products Branch at Singapore National Regulatory Authority, Health Sciences Authority (HSA). During his 10 years tenure in HSA, Dinesh held many different roles, including Senior GMP Inspector at the HSA Inspectorate (PIC/S member), with increasing responsibilities. As the Director, his main role was to manage, oversee and drive the key development, review and administration of the pre-market regulatory framework for western medicines. In that capacity, he was mainly responsible for review of medicinal product dossiers and market authorization of innovative chemical drugs, generics, biotherapeutics, biosimilars, combination products, vaccines, plasma-derived medicines and advanced therapy medicines.

While with HSA, he held the role of rotating chair of four-agency ACSS (Australia, Canada, Switzerland and Singapore) medicinal product work-sharing and harmonisation consortium and sixteen-agency IGDRP (International Generic Drug Regulators Project. Additionally, he held the positions of Chair of ASEAN PPWG Implementation Workgroup and Temporary Advisor at WHO on Biotherapeutics, Biosimilars, Vaccines and National Regulatory Authority Assessment.

Prior to the roles in the regulatory agency, Dinesh held many positions in Pharmaceutical and Medical Device Industry and, in Academia for over 20 years gaining experience in biopharmaceutical QA/QC, GMP, bioanalytical method development and validation, GMP and suppliers auditing, laboratory medicine, diagnostics, and university teaching & research in pathology, parasitology and molecular genetics.
Dinesh received his Ph.D. in Cell and Molecular Biology from the National University of Singapore. He is an American Society for Quality Certified Quality Auditor and Biomedical Auditor. He has also earned certificates in Clinical Trials Management and Healthcare Policy and Governance. Currently, he is the President of Parenteral Drug Association Singapore Chapter.