

CONFERÊNCIA PIC/S – BPF ANVISA CP 653/19



22 - 24 de Julho , 2019 - São Paulo

22 DE JULHO

Dinesh Khokal, Amgen, PDA Singapore

- Breve introdução ao PIC/S
- Sistema da Qualidade Farmacêutico
- Pessoal
- Documentação
- Produção
- Controle de Qualidade
- Reclamações e Recall de Produtos

23 DE JULHO

Dinesh Khokal, Amgen, PDA Singapore

- Fabricação de Medicamentos Estéreis
- Amostragem de Materiais de Embalagem
- Qualificação e Validação
- Amostras de Referência e Retenção
- Gestão do risco
- Preparação para Auditoria PIC/S
- Integridade de Dados

24 DE JULHO ANVISA / PDA BOARD

- Apresentação e discussão da nova proposta CP 653/19

Patrocinador



Parceiro



PLANEJAMENTO

Alexandre Terada
Bruna Vinco
Jaqueline Novais
Leonidas Orjuela
Luis Wenzel
Rose Nascimento

Tathiane Castro
Tatiana Oliveira
Tereza Amaral
Vinicius Paccola
Vitorio Santos
Wolfgang Loscher

As perguntas e dúvidas a ser respondidas durante o evento serão coordenadas pelo equipe de planejamento. Favor enviar no e-mail picsqa@pdabrazil.org

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, a non-profit organization for connecting people, science and regulation.

CONTATO E INFORMAÇÕES

Tel. 11-2894-9730/31 - E-mail: pics@pdabrazil.org

Horario: 8:00 as 17:00

Valor conferência Associados: R\$ 1.200,00 / Não Associados: R\$ 1000,00

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

