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Tugas Compounding and Dispensing

Standart Operating Procedure (SOP)

Laminar Air Flow (LAF)

A. Persiapan

1. Cuci kedua tangan sampai bersih
2. Gunakan APD (Alat Pelindung Diri) yang bersih
3. Pakailah sarung tangan yang sesuai dan bersih
4. Pakailah masker dan penutup kepala yang bersih
5. Bersihkan permukaan LAF dengan etanol 70% atau desinfektan yang tidak mengandung klorin

B. Menyalakan Kabinet

1. Pastikan kabel instrumen telah terhubung dengan arus listrik
2. Nyalakan lampu ultraviolet dengan menekan tombol UV LAMP ON dan tunggu selama 30 menit untuk , lalu lampu UV dimatikan
3. Nyalakan *blower* dengan menekan tombol FAN ON dan nyalakan juga lampu neon, biarkan paling sedikit 5 menit untuk mengurangi kontaminasi dari tempat bekerja

C. Penggunaan LAF

1. Buka kaca pelindung dan masukkan alat yang diperlukan saja selama bekerja ke dalam LAF minimal berjarak 6 inchi dari setiap dinding LAF
2. Semprot tangan dengan etanol 70% sebelum bekerja di LAF
3. Hindari keluar masuknya alat dari/ke dalam LAF untuk mnegurangi resiko kontaminasi
4. HEPA filter tidak boleh tersentuh, terkena cairan pembersih atau bahan lain
5. Lakukan preparasi secara aseptis

Laf Sop Form

Marcel A. Müller



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Validation Standard Operating Procedures Syed Imtiaz Haider, 2006-05-30 Spanning every critical element of validation for any pharmaceutical diagnostic medical device or equipment and biotech product this Second Edition guides readers through each step in the correct execution of validating processes required for non aseptic and aseptic pharmaceutical production With 14 exclusive environmental performance evaluati

Establishing A CGMP Laboratory Audit System David M. Bliesner, 2006-04-20 The first systematic hands on auditing guide for today s pharmaceutical laboratories In today s litigious environment pharmaceutical laboratories are subject to ever stricter operational guidelines as mandated by the FDA and must be able to establish and demonstrate sustainable operational practices that ensure compliance with the current good manufacturing practice CGMP regulations David Bliesner s Establishing a CGMP Laboratory Audit System A Practical Guide is designed to provide laboratory supervisors and personnel with a step by step hands on audit system that they can rely on to ensure their facility remains compliant with all current and future requirements Focusing on a team approach the author uses detailed flowcharts checklists and descriptions of the auditing process to help readers develop a new audit system or upgrade their current system in order to Improve current compliance Demonstrate sustainable compliance Produce data for federal inspections Avoid regulatory action Enhanced with detailed checklists and a wealth of practical and flexible auditing tools on CD ROM this book provides an ideal resource for new and future laboratory personnel and an excellent means for keeping existing industry practitioners up to date on the nuances of operating a consistently compliant pharmaceutical laboratory

Proceedings, 1997

Quality Operations Procedures for Pharmaceutical, API, and Biotechnology Syed Imtiaz Haider, Erfan Syed Asif, 2012-06-06 To stay in compliance with regulations pharmaceutical medical and biotech companies must create quality SOPs that build in the regulatory requirements into actions and describe personal flow internal flow flow of information and processing steps Quality Operations Procedures for Pharmaceutical API and Biotechnology and the accompanying CD ROM take into account all major international regulations such as FDA EU GMP cGMP GLP PDA technical monographs PDA technical reports PMA concepts journals of PDA GCP and industry standard ISO 9000 to be in compliance with documentation guidelines No other resource deals exclusively with the key elements of quality control and quality assurance procedures for pharmaceutical operations and provides hands on templates to be tailored to achieve global regulatory compliance The book provides instant answers about what to include in critical quality assurance and quality control SOPs and how to enhance productivity The CD ROM contains nineteen quality control and thirty three quality assurance SOPs designed so that users can input them into their computers and use their Microsoft Word programs to edit and print these documents The book ensures minimization of the number of documents helping to reduce the nightmare like aura that surrounds an FDA audit The SOPs exclusively refer to the documents specially required for compliance however specific formats are not included to ensure that the electronic templates can be easily used by

pharmaceutical bulk pharmaceutical medical device and biotechnology industries The combination of text and CD ROM presents a ready to use resource on the quality systems of aseptic pharmaceutical non aseptic production and to provide general information and guidelines They comprise a tool that can be used to develop a set of quality SOPs in order to support the road map established for the on time successful start up of the facility operation in compliance with the GMP requirements

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