SOKOL
GxP Services

Crafting GxP Excellence

Sokol GxP Academy Course Catalog

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Sokol GxP Academy

We embrace a Skills-First approach.

Our Academy is open to students and incumbent workers with or without a college degree and offers comprehensive programs that provide certifications in GMP (Deviation Management, GMP Foundations, GMP Cleaning, Aseptic Manufacturing), Professional Development (soft skills), and CQV (Commissioning, Qualification, and Validation). This rigorous training empowers participants with the essential skills needed to succeed in the pharmaceutical industry. We enable graduates to earn a sustainable income and to unlock opportunities for significant career growth — ultimately building up our communities and creating lasting impact in our world.

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Learning Pathway: GxP Foundations	
Description	**Learning Objectives**
GxP Foundations Forge a strong and lifelong foundation for growth in the biotech / pharmaceutical industry. You will learn how to speak the language and better understand the industry. This training pathway includes: • **Good Manufacturing Practices (GMP).** • **Good Documentation Practices (GDocP).** • **Cleanroom Success.** • **Audit Communication.** • **Demystifying Pharma.** **Duration**: 3 Days.	• Understand Good Manufacturing Principles (GMP) principles and begin to familiarize yourself with the roles and responsibilities of different functional groups within the industry. ◆ **Topics covered**: ▪ Fundamental principles and regulatory standards of GMP. ▪ History and purpose of GMP. ▪ Personnel control. ▪ Facility, utilities, and equipment controls. ▪ Validation. ▪ Quality control. ▪ Batch release. ▪ Change control. ▪ Deviation control. ▪ Documentation. ▪ Regulatory inspections. • Gain a thorough understanding of Good Documentation Practices (GDocP) to ensure clarity in GMP terminology and establish a solid foundation for executing and documenting work in compliance with regulatory standards. ◆ **Topics covered**: ▪ Introduction to Good Documentation Practices. ▪ Core Principles of GDocPs. ▪ Practical Application of GDocPs. ▪ Common pitfalls and how to avoid them. ▪ Advanced GDocP Practices. • Develop the essential skill of effective communication with auditors, crucial for all professionals engaged in Good Manufacturing Practices (GMP). This course will equip you with the techniques to deliver pertinent information while maintaining concise and relevant responses to inquiries. ◆ **Topics covered**: ▪ Understanding Auditor Expectations. ▪ Techniques for Clear Responses. ▪ Delivering Pertinent Information. ▪ Maintaining Concise Communication.

Course	Learning Objectives
Good Manufacturing Practices: Building a Strong Foundation for Industry Success	• Grasp the fundamental principles and regulatory standards of GMP. • Acquire skills to implement GMP in production planning and quality assurance. • Recognize the significance of precise documentation and record management. • Investigate the role of GMP in minimizing errors, ensuring regulatory compliance, and improving overall operational effectiveness. • Understand the responsibilities of personnel, the importance of effective training programs, and the maintenance of compliant facilities.
Good Documentation Practices: A Comprehensive Guide	• The significance of adhering to GDPs to ensure reliable data and meet regulatory standards. • The role of GDPs in ensuring patient safety by maintaining the accuracy and reliability of data. • Guidelines for maintaining data integrity through proper recording, correcting, and managing practices. • Understanding and demonstrating compliance with regulatory requirements.
Cleanroom Success: Key Concepts and Best Practices	• Intricate details of facility design that ensure optimal conditions for sensitive processes. • Various sources of contamination that can compromise the integrity of cleanroom environments and how to effectively mitigate these risks. • Importance of understanding traffic flow patterns within cleanrooms, vital for maintaining cleanliness and efficiency. • Gowning requirements and procedures, emphasizing the significance of personal protective equipment in preventing contamination. • Expected behaviors within cleanrooms that contribute to a sterile environment. • Protocols for environmental monitoring to ensure compliance with industry standards. • Best practices for cleanroom cleaning, essential for maintaining the integrity of these controlled environments.

Course	Learning Objectives
Effective Communication with Auditors	• Understanding Auditor Expectations: Learn the key expectations auditors have during GMP audits to ensure compliance and effective communication. • Techniques for Clear Responses: Master techniques to provide clear and precise responses to auditor inquiries, enhancing your communication skills. • Delivering Pertinent Information: Develop the ability to deliver relevant and accurate information to auditors, ensuring all necessary details are covered. • Maintaining Concise Communication: Acquire skills to maintain concise and to-the-point communication, avoiding unnecessary details during audits.
Demystifying Pharma Corporate Structures for New Entrants	• Identify key roles within a pharmaceutical company. • Understand the interactions between different departments. • Grasp the essentials of corporate governance and compliance. • Explore the importance of corporate culture, including diversity and inclusion. • Discover opportunities for career development and professional growth within the industry. • Navigate and adapt to the pharmaceutical corporate environment effectively.

Learning Pathway: GMP Cleaning	
Description	**Learning Objectives**
GMP (Good Manufacturing Practice) Cleaning Training This training pathway will provide you with the comprehensive knowledge and practical skills needed to effectively keep a facility clean while staying compliant. This training pathway includes: • **Overview of Good Manufacturing Practice (GMP) and Cleaning Fundamentals.** • **Personal Hygiene, Gowning, and Entry Protocols.** • **Cleaning Methods and Tools.** • **Documentation and SOP (Standard Operating Procedure) Compliance.** Prerequisites*: • GxP Foundations. *Equivalencies considered on a case-by-case basis. **Duration**: 5 Days.	• Understand GMP principles and why cleaning is critical to compliance and safety. ◆ **Topics Covered:** ▪ Introduction to GMP. ▪ Types of contamination. ▪ Industry standards and regulatory bodies. • Learn how personal habits and hygiene practices prevent contamination. ◆ **Topics Covered:** ▪ Gowning and de-gowning procedures for cleanrooms ▪ Cleanroom entry/exit protocols. ▪ Proper donning, use, and disposal of PPE (Personal Protective Equipment). • Master cleaning techniques and proper use of tools. ◆ **Topics Covered:** ▪ Cleaning of different surfaces. ▪ Difference between cleaning, sanitization, and disinfection. ▪ Approved cleaning agents and disinfectants, and cleaning tools. • Understand documentation's role in GMP compliance. ◆ **Topics Covered**: ▪ Good Documentation Practices (GDocP). ▪ Cleaning logs and records.

Course	Learning Objectives
Overview of GMP (Good Manufacturing Practice) and Cleaning Fundamentals	• Understand the key principles of Good Manufacturing Practice (GMP). • Identify the roles of regulatory bodies (FDA, EMA, WHO) in setting industry standards. • Differentiate between various types of contamination: chemical, biological, and cross-contamination. • Explain the distinctions between cleaning, sanitization, and disinfection. • Recognize the impact of cleaning on patient safety and product quality.
Personal Hygiene, Gowning, and Entry Protocols	• Understand how personal habits and hygiene impact cleanroom environments. • Follow proper gowning and de-gowning procedures for cleanroom operations. • Learn cleanroom entry/exit protocols to prevent contamination. • Understand the correct technique for handwashing and glove use. • Use and disposal of Personal Protective Equipment (PPE) according to guidelines.
Cleaning Methods and Tools	• Understand cleaning procedures for various surface types (e.g., floors, walls, equipment). • Identify approved cleaning agents and disinfectants for use in GMP environments. • Select appropriate tools such as low-lint wipes, mops, brushes, and 3-bucket systems for specific tasks. • Recognize the importance of using correct methods to avoid recontamination.
Documentation and SOP (Standard Operating Procedure) Compliance	• Understand Good Documentation Practices (GDP) and their role in compliance. • Identify essential elements of cleaning logs and records. • Know what information to document, how, and when to complete cleaning logs. • Recognize the importance of consistent, accurate, and timely documentation to maintain data integrity.

Learning Pathway: Aseptic Manufacturing	
Description	**Learning Objectives**
Aseptic Manufacturing Aseptic principles and techniques are critical in preventing contamination to life saving products. This training pathway will provide you with the comprehensive knowledge and practical skills needed to work in this highly regulated environment. This training pathway includes: • **Aseptic Gowning.** • **Aseptic Processing Principles.** • **Aseptic Techniques.** • **Contamination Control Principles.** Prerequisites*: • GxP Foundations. • GMP Cleaning. *Equivalencies considered on a case-by-case basis. **Duration**: 3 Weeks.	• Aseptic Gowning. • Preventing Contamination Methods. • Regulatory Compliance Standards. • Practical Aseptic Skills. • Comprehensive Knowledge Base.

Course	Learning Objectives
Aseptic Gowning	• Aseptic Gowning Procedures: Learn the proper techniques for aseptic gowning to ensure a sterile environment and prevent contamination. • Understand the importance of proper gowning. • Step-by-step gowning procedures. • Common mistakes and how to avoid them.
Aseptic Processing Principles	• Contamination Prevention Methods: Understand various methods to prevent contamination in the production of life-saving products. • Types of contamination and their sources. • Best practices for contamination control. • Monitoring and maintaining a contamination-free environment.
Aseptic Techniques	• Regulatory Compliance Standards: Gain knowledge of the regulatory standards that govern aseptic techniques and ensure compliance. • Analyze important regulations and guidelines that impact organizational practices. • Develop effective compliance strategies and documentation to meet regulatory requirements. • Evaluate the implications of non-compliance with regulatory standards in aseptic techniques. • Apply regulatory guidelines to real-world scenarios in aseptic practices. • Create a comprehensive compliance checklist tailored to specific organizational needs.
Contamination Control Principles	• Practical Aseptic Skills: Develop practical skills necessary for working in a highly regulated aseptic environment. • Hands-on training exercises. • Real-world application of aseptic techniques. • Continuous improvement and skill assessment.

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Learning Pathway: Professional Development	
Description	**Learning Objectives**
Professional Development Soft skills are critical in ensuring cohesive team dynamics, project completion, and in acquiring and maintaining employment. Develop new skills and refresh those needing further development. It is a strength to recognize and identify areas needing improvement. Included with all other course pathways or as an independent option, we will strengthen your soft skills and prepare you for job search and placement. This training pathway includes: • **Resume Writing and Review.** • **Interview Coaching.** • **Emotional Intelligence (EQ) and Applications for Leadership.** **Duration**: Varies.	• Sokol will assist you in crafting an effective and purposeful resume. You will gain insight into the rationale behind presenting your work, enabling you to develop a valuable lifelong skill. ◆ **Topics Covered:** ▪ Understanding Resume Purpose. ▪ Highlighting Key Achievements. ▪ Tailoring to Job Description. ▪ Formatting for Impact. • You will learn effective interviewing techniques for both virtual and in-person settings. You will learn to communicate precisely while providing informative responses, ensuring you make a positive impression and maximizing your opportunity for employment. ◆ **Topics Covered**: ▪ Virtual Interview Preparation. ▪ In-Person Interview Strategies. ▪ Precise Communication Skills. ▪ Maximizing Employment Opportunities. • You will learn about Emotional Intelligence (EQ) and its applications for leadership, focusing on how it contributes to professional success and personal fulfillment. ◆ **Topics Covered**: ▪ Understanding EQ Basics. ▪ EQ in Professional Success. ▪ EQ for Personal Fulfillment. ▪ Leadership Applications of EQ.

Course	Learning Objectives
Resume Writing and Review	• Understanding Resume Purpose: Learn the importance of a resume and how it serves as a marketing tool to showcase your skills and experiences. • Highlighting Key Achievements: Discover how to effectively highlight your most significant accomplishments to make your resume stand out to potential employers. • Tailoring to Job Description: Understand the necessity of customizing your resume for each job application to align with the specific requirements and expectations of the role. • Formatting for Impact: Gain insights into the best practices for formatting your resume to ensure it is visually appealing and easy to read.
Interview Coaching	• Virtual Interview Preparation: Learn how to set up your technology, choose an appropriate background, and present yourself professionally in a virtual interview setting. • In-Person Interview Strategies: Discover techniques for making a strong first impression, including proper attire, body language, and effective question responses. • Precise Communication Skills: Master the art of clear and concise communication to ensure your responses are informative and impactful during interviews. • Maximizing Employment Opportunities: Understand how to highlight your strengths and experiences to leave a lasting positive impression on potential employers.
Emotional Intelligence (EQ) and Applications for Leadership	• Understanding EQ Basics: Gain a foundational understanding of Emotional Intelligence, including its key components and how it differs from traditional intelligence. • EQ in Professional Success: Learn how EI contributes to professional success by enhancing communication, teamwork, and decision-making skills. • EQ for Personal Fulfillment: Discover how Emotional Intelligence can lead to personal fulfillment by improving self-awareness, empathy, and emotional regulation. • Leadership Applications of EQ: Explore how leaders can apply Emotional Intelligence to inspire and motivate their teams, fostering a positive and productive work environment.

Learning Pathway: Deviation Management	
Description	**Learning Objectives**
Deviation Management & Corrective Action, Preventive Action (CAPA) for Quality Excellence This course will help you to confidently identify, document, assess, and investigate deviations while preventing future occurrences. Learn industry-leading practices for effective deviation management, root cause analysis, and CAPA implementation that drive long-term results. This training pathway includes: • **Fundamentals of Deviations and CAPA Processes.** • **Deviations Investigating and Conducting Root Cause Analysis.** • **CAPA Plans: Development and Evaluation.** Prerequisites*: • GxP Foundations. *Equivalencies considered on a case-by-case basis. **Duration**: 2 weeks.	• Understand the fundamentals of deviations and CAPA processes in maintaining compliance. ◆ **Topics Covered:** ▪ Definition and regulatory significance of deviations. ▪ Key preventive measures. ▪ Overview of the deviation lifecycle. • Master the process of investigating deviations and conducting root cause analysis effectively. ◆ **Topics Covered:** ▪ Step-by-step investigation process for deviations. ▪ Techniques for root cause analysis. ▪ Best practices for documenting findings during investigations. • Develop and evaluate effective CAPA plans to ensure successful corrective and preventive actions. ◆ **Topics Covered:** ▪ Strategies for creating and implementing effective CAPA plans. ▪ Monitoring CAPA progress and assessing implementation. ▪ Methods for conducting effectiveness checks on CAPAs. ▪ The role of AI in enhancing CAPA processes and deviation management.

Course	Learning Objectives
Fundamentals of Deviations and CAPA Processes	• Define what a deviation is. • Identify measures to prevent deviations. • Distinguish between a corrective action and a preventive action. • Describe the deviation lifecycle and its role in maintaining compliance.
Deviations Investigating and Conducting Root Cause Analysis	• Understand the deviation investigation process. • Learn root cause analysis techniques (e.g., 5 Whys, Ishikawa Diagram). • Develop data collection methods for deviation investigations. • Practice documenting findings accurately and effectively.
CAPA Plans: Development and Evaluation	• Learn how to develop effective CAPA plans. • Understand CAPA implementation and follow-up. • Perform effectiveness checks to ensure successful corrective and preventive actions. • Discuss AI's role in enhancing CAPA processes and deviation management.

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Learning Pathway: Commissioning, Qualification, and Validation (CQV)

Description	Learning Objectives
Commissioning, Qualification, and Validation (CQV) is a highly sought after and necessary function in biotech / pharmaceuticals. Prerequisites*: • GxP Foundations. • GMP Cleaning. *Equivalencies considered on a case-by-case basis. This training pathway includes: • **Commissioning of Equipment, Utilities and Facilities Principles.** • **Computer System Validation (CSV).** • **System Development Lifecycle.** • **Design Requirements and Qualification (DR and DQ) Development.** • **System Level Impact Assessment (SLIA).** • **User Requirements Specification (URS) Development.** • **Installation and Operational Qualification (IOQ).** • **Performance Qualification (PQ).** • **Validation Summary Report (VSR).** • **Requirements Traceability Matrix (RTM).** • **Risk Based Approach in Qualification (Verification).** • **Site Validation Master Plan (VMP).** • **Failure Mode and Effect Analysis (FMEA).** • **P&ID Walkdown Principles.** • **Qualification of Controlled Temperature Units (CTU) Qualification Principles.** • **Validation Equipment Use (Kaye and Ellab).** • **Sterilization Principles.** • **Steam in Place (SIP) Sterilization Validation.** • **Autoclave Steam Sterilization Validation.** • **Depyrogenation oven validation.** • **Environmental Monitoring (EM).** • **Environmental Monitoring Performance Qualification (EMPQ).** • **Airflow Visualization (Smoke) Studies for BSC.** • **Airflow Visualization (Smoke) Studies for Aseptic Processing Areas.** • **Clean Air Equipment (UDAF, RABS, and Isolators) Qualification Principles.** • **Cleaning Validation Principles.** • **Clean in Place (CIP) Validation Principles.** **Duration:** 1-8 Weeks.	• CQV: General. • CQV: Cold Storage. • CQV: Contamination Control. • CQV: Sterilization Validation. • Project Management in CQV. • Airflow Visualization Studies.

Course	Learning Objectives
Commissioning of Equipment, Utilities and Facilities Principles	• Master the key steps and documentation required for commissioning equipment, utilities, and facilities. • Gain a clear understanding of qualification deliverables and their specific requirements. • Learn the differences and relationships between commissioning, qualification, and validation.
Computer System Validation (CSV)	• Learn the lifecycle approach to CSV, emphasizing GxP compliance, data integrity, and system reliability. • What is 21 CFR Part 11, Annex 11, and GAMP 5, and how they apply to the validation of computerized systems in regulated environments. • Explore different testing strategies, including functional, risk-based, and performance testing.
System Development Lifecycle	• What are the phases of the System Development Lifecycle (SDLC) in GxP-regulated environments? • Understand how to meet user requirements through design, validation, and maintenance. • Explore the integration of risk management into each stage of system development.
Design Requirements and Qualification (DR and DQ) Development	• Learn to develop Design Requirements (DR) that meet user and regulatory needs. • Explore how DR and DQ fit into the overall validation strategy. • Understand how to verify designs through Design Qualification (DQ).
System Level Impact Assessment (SLIA)	• Learn how to conduct system-level impact assessments to evaluate effects on product quality. • Identify critical systems that require qualification. • Explore methods for documenting and managing risks related to system impacts.
User Requirements Specification (URS) Development	• Learn to create detailed User Requirements Specifications (URS) that capture functional and compliance needs. • Why development of comprehensive URS requires collaboration with all stakeholders. • Understand how URS supports system design and validation.

Course	Learning Objectives
Installation and Operational Qualification (IOQ)	• How to plan and execute IQ and OQ for systems and equipment. • Understand the documentation required for IQ/OQ activities. • What is required to assemble comprehensive Engineering Turn Over Package (ETOP).
Performance Qualification (PQ)	• Understand the purpose of PQ and its role in verifying system performance. • Learn how to design a comprehensive PQ protocol.
Validation Summary Report (VSR)	• Learn how to compile qualification and validation results into a comprehensive Validation Summary Report. • Understand how to summarize critical findings, deviations, and corrective actions. • Explore methods for presenting data in a clear, compliant format.
Requirements Traceability Matrix (RTM)	• How to create and maintain an RTM that tracks system requirements. • Understand how to trace requirements through different phases of validation. • Learn how RTM can be used to manage compliance and project scope.
Risk Based Approach in Qualification (Verification)	• How to apply a risk-based approach to qualification activities. • Understand how to focus on critical systems that directly impact product quality and safety. • Develop skills in documenting risk assessments.
Site Validation Master Plan (VMP)	• The purpose of a Site Validation Master Plan (VMP) as a strategic document that outlines the approach and scope of validation activities across a site. • Learn the key components of a comprehensive VMP, including validation strategy, responsibilities, deliverables, and risk assessments.

Course	Learning Objectives
Failure Mode and Effect Analysis (FMEA)	• How to identify potential failure points through FMEA. • Develop skills in assessing the impact and likelihood of failure modes. • Explore strategies for implementing risk mitigation to prevent failures.
P&ID Walkdown Principles	• Learn how to conduct P&ID walkdowns to verify system design and installation. • Understand how to identify and document discrepancies between installed systems and design documentation.
Qualification of Controlled Temperature Units (CTU) Qualification Principles	• Understand the key principles of CTU qualification and regulatory requirements. • Learn to choose the right validation system and place mapping sensors effectively. • Develop skills to analyze and interpret CTU mapping results for compliance.
Validation Equipment Use (Kaye and Ellab)	• How to configure and operate Kaye and Ellab validation equipment for temperature mapping. • Develop skills in analyzing and interpreting validation data from these tools.
Sterilization Principles	• Learn the principles of various sterilization methods, including steam, dry heat, and chemical sterilization. • Understand how to validate sterilization processes to achieve microbial inactivation. • Explore methods for documenting sterilization validation results.
Steam in Place (SIP) Sterilization Validation	• How to validate SIP sterilization processes for closed systems. • Understand the steps involved in executing SIP validation protocols. • What is Biological Indicator (BI) and how to use it.

Course	Learning Objectives
Autoclave Steam Sterilization Validation	• Learn to validate autoclave steam sterilization processes, ensuring consistent microbial inactivation. • Understand the critical parameters of autoclave validation. • Gain knowledge of Biological Indicators (BI), their proper handling, and how to use them effectively in validation studies.
Depyrogenation Oven validation	• Learn the principles of validating depyrogenation ovens for pyrogen removal. • Understand how to conduct temperature mapping for depyrogenation processes.
Environmental Monitoring (EM)	• Understand the purpose of an EM program in controlled environments and its critical role in contamination control. • Gain expertise in the equipment used for environmental monitoring and how to apply it effectively in maintaining cleanroom standards.
Environmental Monitoring Performance Qualification (EMPQ)	• What is the purpose and significance of EMPQ in ensuring cleanroom compliance? • Learn the key components of EMPQ, including protocol development, testing criteria, and data analysis. • Gain knowledge of the equipment used in EMPQ.
Airflow Visualization (Smoke) Studies for BSC	• Understand how airflow patterns impact containment and contamination control. • Learn how to conduct smoke studies to verify airflow patterns in Biological Safety Cabinets (BSC).
Airflow Visualization (Smoke) Studies for Aseptic Processing Areas	• How airflows contribute to contamination control in sterile environments. • Learn to perform airflow visualization (smoke) studies in aseptic processing areas. • Gain knowledge of the equipment used for Airflow Visualization studies.

Course	Learning Objectives
Clean Air Equipment (UDAF, RABS, and Isolators) Qualification Principles	• Learn the qualification principles for clean air equipment, including UDAF, RABS, and isolators. • Understand how to assess airflow and contamination control for these systems.
Cleaning Validation Principles	• Understand how to verify cleaning effectiveness and regulatory compliance. • Learn to develop and execute cleaning validation protocols to prevent cross-contamination.
Clean in Place (CIP) Validation Principles	• Learn how to validate Clean-in-Place (CIP) systems for effective cleaning. • Understand how to create and execute CIP validation protocols. • Develop skills in documenting CIP validation activities.

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