Health care and Pharmaceutical

Computer System Validation (CSV)

Curriculum

Program Outline :

Module 1:Fundamentals of Computer System Validation (CSV

1.**System Requirements Definition:** Clearly defining both functional and non-functional requirements of the system to ensure it meets its intended use.

2.**Risk Management:** Conducting a thorough risk assessment to identify potential issues and implementing mitigation strategies to ensure system reliability and compliance.

3.**Validation Planning:** Developing a comprehensive validation plan that outlines the scope, objectives, resources, and timeline for the validation process.

4.**Testing and Documentation:** Executing rigorous testing protocols to verify system performance and integrity, and maintaining detailed documentation of all validation activities.

5.**Change Control and Maintenance:** Implementing robust change control procedures to manage system modifications and ensuring ongoing maintenance to keep the system compliant and effective

Module 2:Advanced Computer System Validation (CSV)

1.Risk-Based Approach: Implementing a risk-based approach to prioritize validation activities based on the potential impact on product quality and patient safety.

2.Lifecycle Management: Managing the entire lifecycle of the computer system, from initial concept and design through to retirement, ensuring continuous compliance and performance.

3.Advanced Testing Techniques: Utilizing advanced testing techniques, such as automated testing and stress testing, to ensure system robustness and reliability.

4.Regulatory Intelligence: Staying updated with the latest regulatory requirements and guidelines from agencies such as the FDA, EMA, and ICH to ensure compliance.

5.Data Integrity and Security: Ensuring data integrity and security through rigorous validation processes, including encryption, access controls, and audit trails.

Module 3:Practical Applications

1**. Patient Care and Management:**
Medication Therapy Management (MTM): Pharmacists optimize medication regimens to improve therapeutic outcomes and reduce adverse effects.

2**. Clinical Practice:**
Patient Counseling: Educating patients on proper medication use, potential side effects, and lifestyle modifications to enhance health outcomes.

3. **Pharmaceutical Research and Development:**
Drug Discovery and Development: Conducting research to discover new medications and develop existing ones

4. **Healthcare Technology and Innovation:**
Telemedicine: Using telehealth platforms to provide remote consultations, follow-ups, and health monitoring

Module 4: Capstone Project
1.**Impact of Telemedicine on Patient Outcomes**
Analyze the effectiveness of telemedicine in improving patient outcomes, especially for chronic disease management .

2.**Pharmaceutical Waste Management**
Develop strategies to reduce pharmaceutical waste and its environmental impact.

3.**Medication Adherence in Elderly Patients**
Investigate factors affecting medication adherence among elderly patients and develop interventions to improve adherence.

4.**Implementation of an Electronic Health Records (EHR) System**
Assess the challenges and benefits of implementing an EHR system in a healthcare facility

Elective Modules
Advanced Pharmacology: Deep dive into the mechanisms of action, side effects, and interactions of various drugs.

Clinical Research Methods: Learn about designing and conducting clinical trials, data analysis, and ethical considerations.

Health Informatics: Study the use of information technology in healthcare, including electronic health records and data management.

Global Health: Explore health issues and solutions in a global context, including international health policies and practices

Websites:

- https://chools.in/
- https://ramaqchools.com/
- https://www.choolsgroup.com/