

# 21 CFR Part 11 Validation



**The Client:** Client is Asia's leading biopharmaceutical company which manufactures generic active pharmaceutical ingredients.



## Business Requirement



Validate the cloud based Learning Management System for 21 CFR Part 11 regulatory compliance



Design and execute test cases for Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)



End to end validation for different user roles and document all validation activities including test protocols, test scripts, test evidences and test reports



## Our Solutions



Leveraged our jumpstart kit that includes Template, Guidelines, Checklists and Reports for 21 CFR Part 11 assessments



Developed and executed 1500+ test cases for IQ, OQ & PQ and 73 critical defects were reported



Performed exploratory testing as value addition and proposed a list of recommendations from user perspective



Created traceability Matrix that includes test cases linking requirements of 21 CFR Part 11



14 test cases were developed and reported to assess the system for 21 CFR Part 11 compliance



## Business Impact



Successfully passed the external compliance audit



Documentation for all the validation activities with evidences for the purpose of audit trail

**Technologies:** Software : Microsoft Azure Cloud service | Defect tracking : Customized tool specialized for project

# 21 Cfr Part 11 Validation

**Liyong Dong**



**21 Cfr Part 11 Validation:**

21 Cfr Part 11 Validation: Bestsellers in 2023 The year 2023 has witnessed a remarkable surge in literary brilliance, with numerous compelling novels captivating the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the captivating narratives that have captivated audiences this year. 21 Cfr Part 11 Validation : Colleen Hoover's "It Ends with Us" This poignant tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover skillfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can prevail. Uncover the Best : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids compelling storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Discover the Magic : Delia Owens "Where the Crawdads Sing" This evocative coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens crafts a tale of resilience, survival, and the transformative power of nature, captivating readers with its evocative prose and mesmerizing setting. These top-selling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a brilliant and gripping novel that will keep you speculating until the very end. The novel is a warning tale about the dangers of obsession and the power of evil.

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