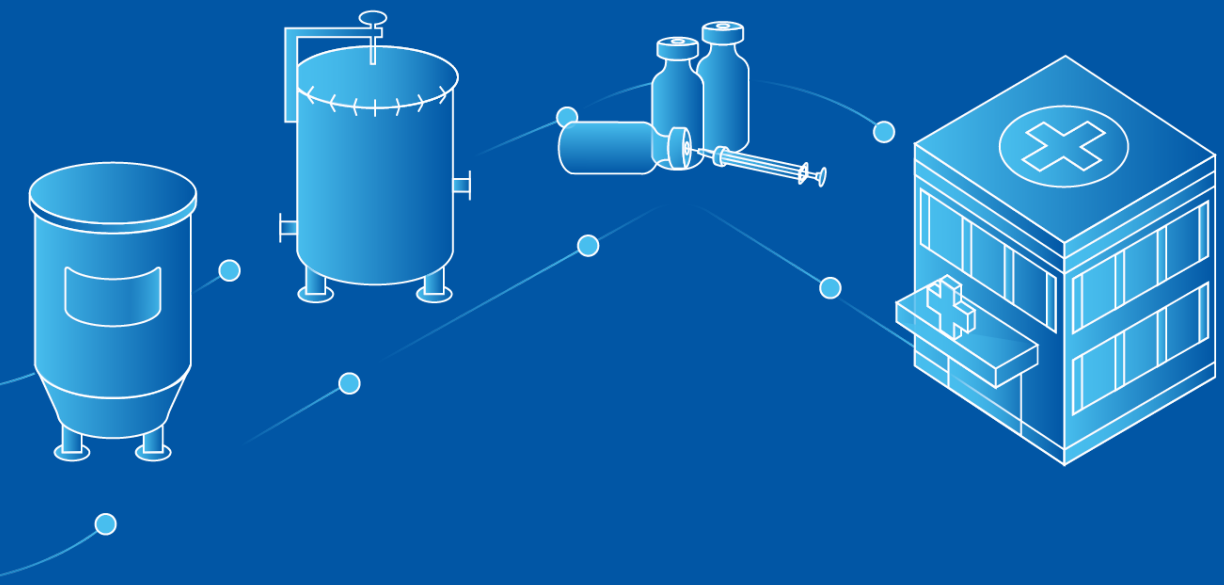
ZENITH TECHNOLOGIES
A **Cognizant** Company

Commissioning, Qualification and Validation



Delivering Excellence in Automation, MES and Digital Manufacturing Direct to the Life Science Industry

Powering Patient Health
www.zenithtechnologies.com

Commissioning, Qualification and Validation (CQV)

+ Computer Systems Validation (CSV) programme delivery
+ Development of risk-based approaches to testing
+ Vigorous testing, validation and quality assurance
+ Facility start up and hyper care
+ Commissioning, Qualification and Validation (CQV) team support

Testing, validation and quality assurance guaranteed

Challenges

01 Implementing a risk-based approach to the project lifecycle

02 Creating CSV plans that support commissioning plans

03 Resourcing FAT Teams

04 Executing Automation Test protocols to support CTPs

05 Supporting CQV teams with Automation & MES expertise

06 Change Control Execution

07 Cost & time taken for CSV

The true test of the success of Automation, MES and Quality Control (QC) Lab Software is when it arrives on site. Ensuring the Commissioning, Qualification and Validation (CQV) process runs smoothly is critical to project success and it is a journey that starts early in the project lifecycle with the Computer Systems Validation (CSV) plan.

Services

The full range of services available from Zenith's CQV team is:

CSV TESTING AND SOFTWARE TEAMS

01 Creation of CSV Master Plan

02 Execution of the full risk management lifecycle including the execution of the risk assessments driving actions

03 Provision of site CSV teams with managed oversight and reporting

04 Provision of Factory Acceptance Testing (FAT) teams

05 Provision of Automation, MES and QC Lab IT resources to support CQV

Meeting your challenges

The CSV plan and execution ensures that the delivered manufacturing systems satisfy regulatory expectations. Zenith Technologies ensure that your software and systems are fit for intended use and satisfy the requirements for design, installation, operation and performance. Our approach integrates CSV with CQV and applies the concepts and principles outlined in:

01 FDA Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach

02 ASTM E2500 - 13 Standard Guide for Specification

03 Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

04 International Council for Harmonisation (ICH)* Framework

05 ISPE – GAMP 5 Guide: Compliant GxP Computerized Systems

* ICH Q8 (R2) Pharmaceutical development
ICH Q9 Quality risk management
ICH Q10 Pharmaceutical quality system
ICH Q11 Development and manufacture of drug substance

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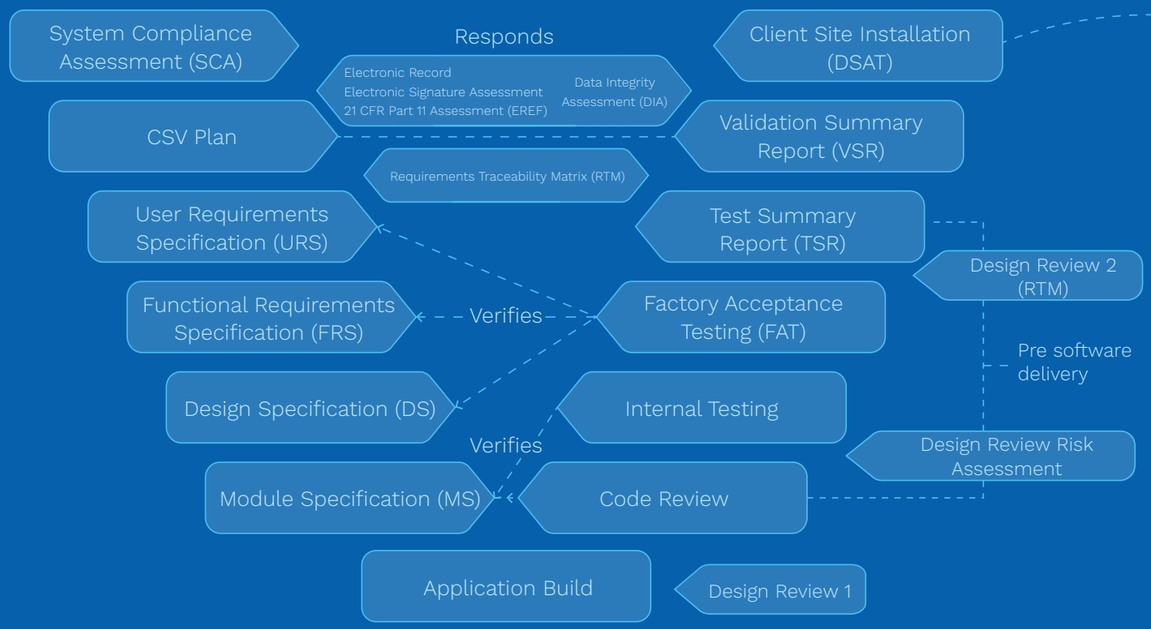
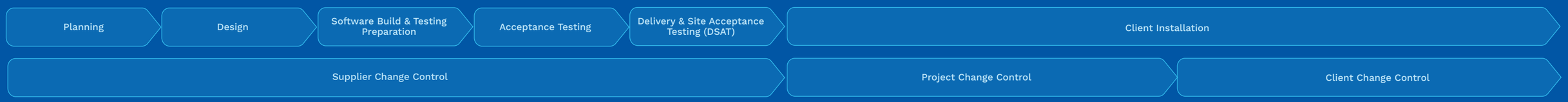
Delivering Qualified Software

Zenith CSV Activities



Zenith/ Client CSV Activities



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Your Global Life Science Partner

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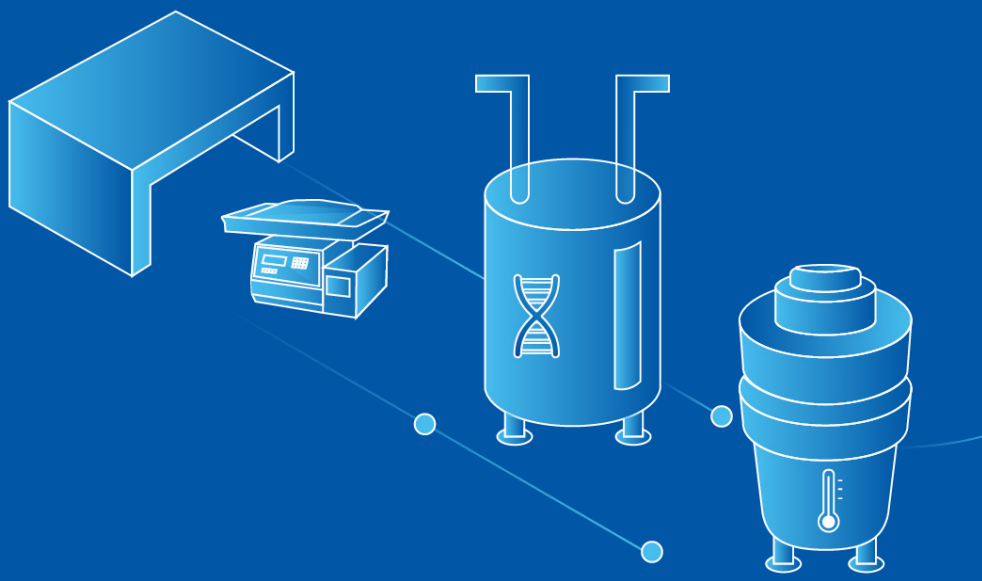

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Great Place To Work.

Cork Chamber vodafone CORK COMPANY OF THE YEAR AWARDS 2019

Deloitte Best Managed Companies 2019 Deloitte.

PHARMA INDUSTRY AWARDS 2018 WINNER PHARMA SUPPLIER OF THE YEAR

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