

Fast, agile & compliant

Achieve compliance for innovations on
SAP BTP in the Life Science industry with
Cloud Service Qualification

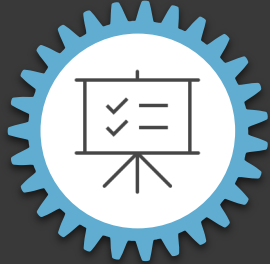
KEY MOTIVATIONS FOR INTRODUCTION OF SAP BTP

- Enable fast & agile business innovations
- Use business-ready services
- Decouple from internal SAP ERP (or S/4HANA) release cycles
- Centralized platform for data, process and interface management
- Shorten time to value for business



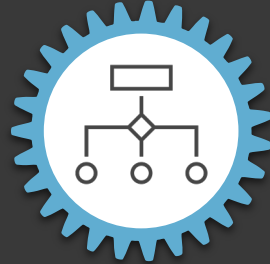
What are the prerequisites to operate applications GxP compliant on SAP BTP?

P36 APPROACH TO GxP COMPLIANCE IN THE CLOUD



ORGANIZATIONAL SETUP

Establish Quality Management, GxP Trainings and Change Management



SDLC & OPERATIONS

Set up Standard Operating Procedures (SOP) for Software Development Lifecycle and operational Support



CONTRACTUAL AGREEMENTS

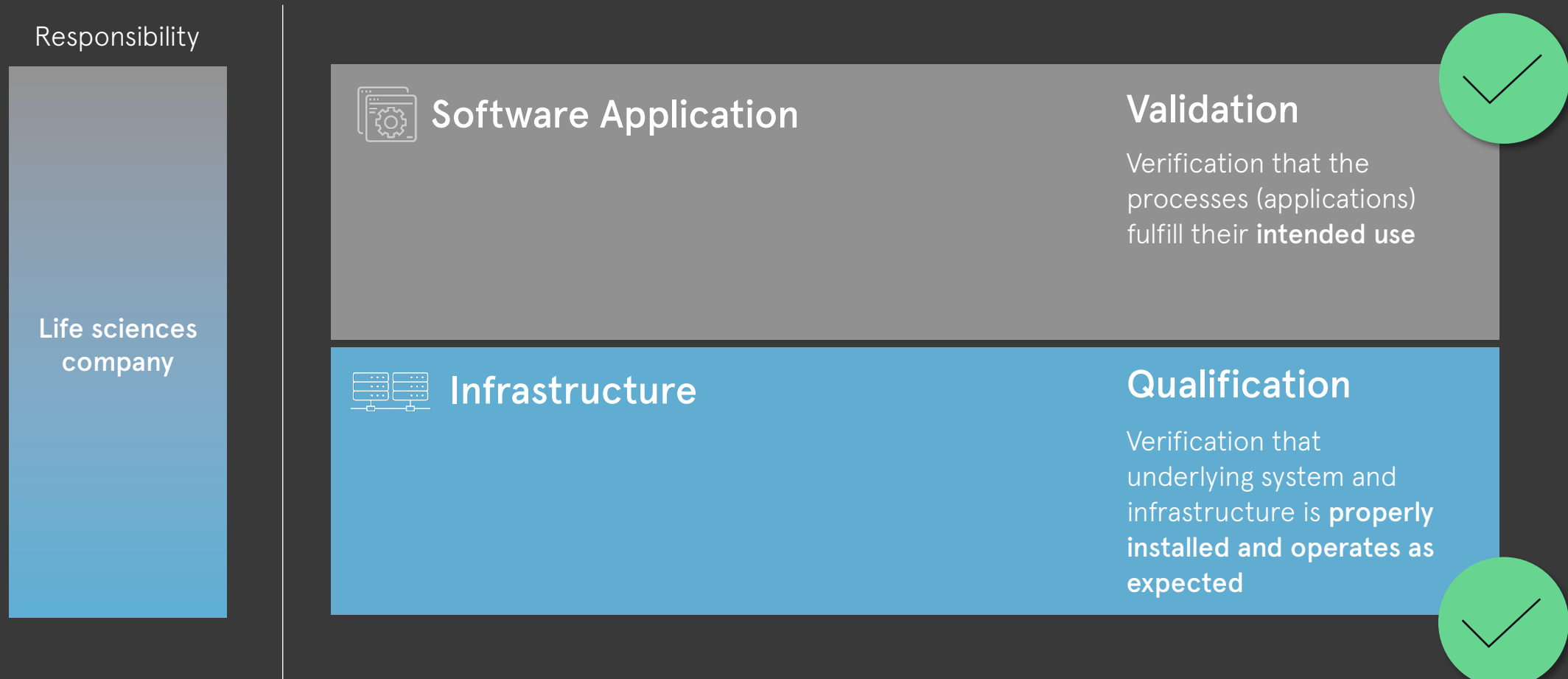
Establish GxP requirements in your supplier/customer contracts w/SLAs and supplier assessments



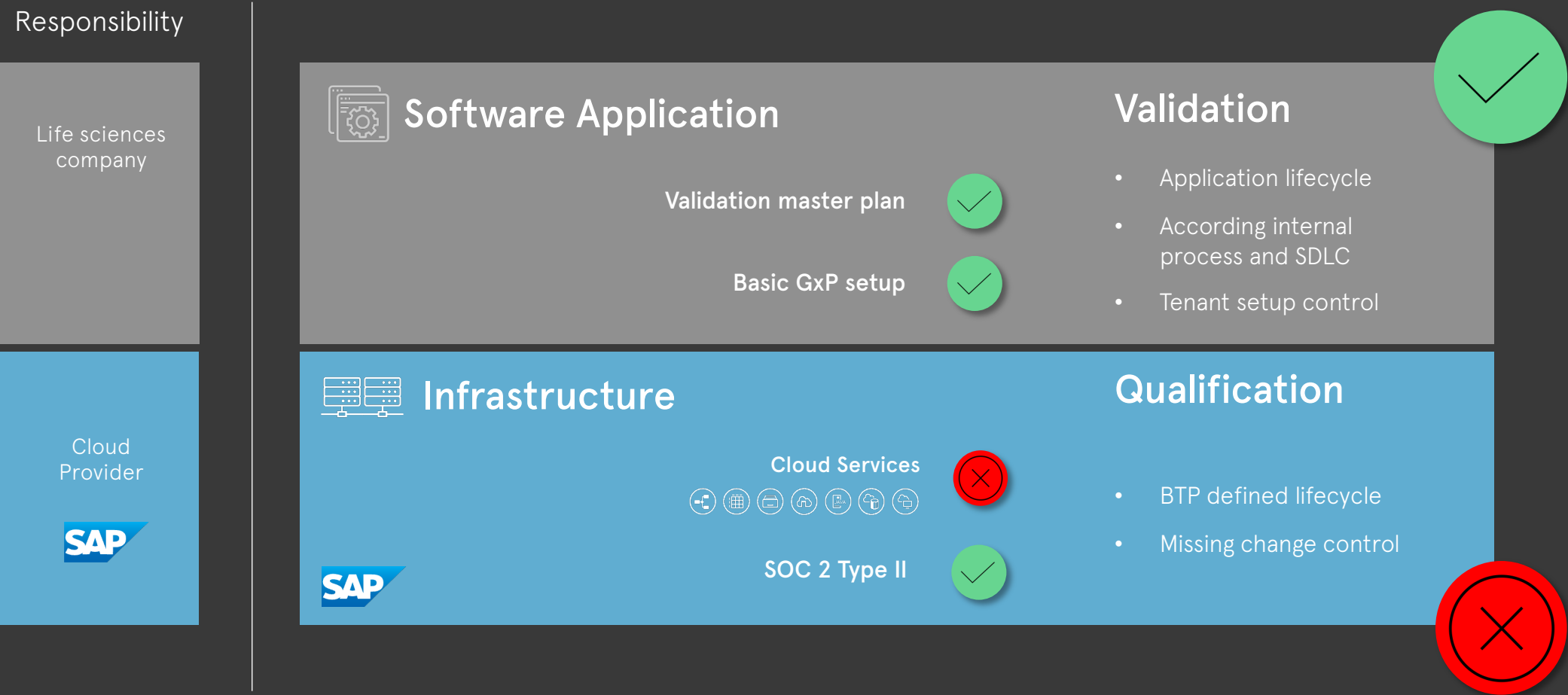
ENSURE PLATFORM QUALIFICATION

Introduce a Cloud Service Qualification Framework to continuously monitor the compliance status

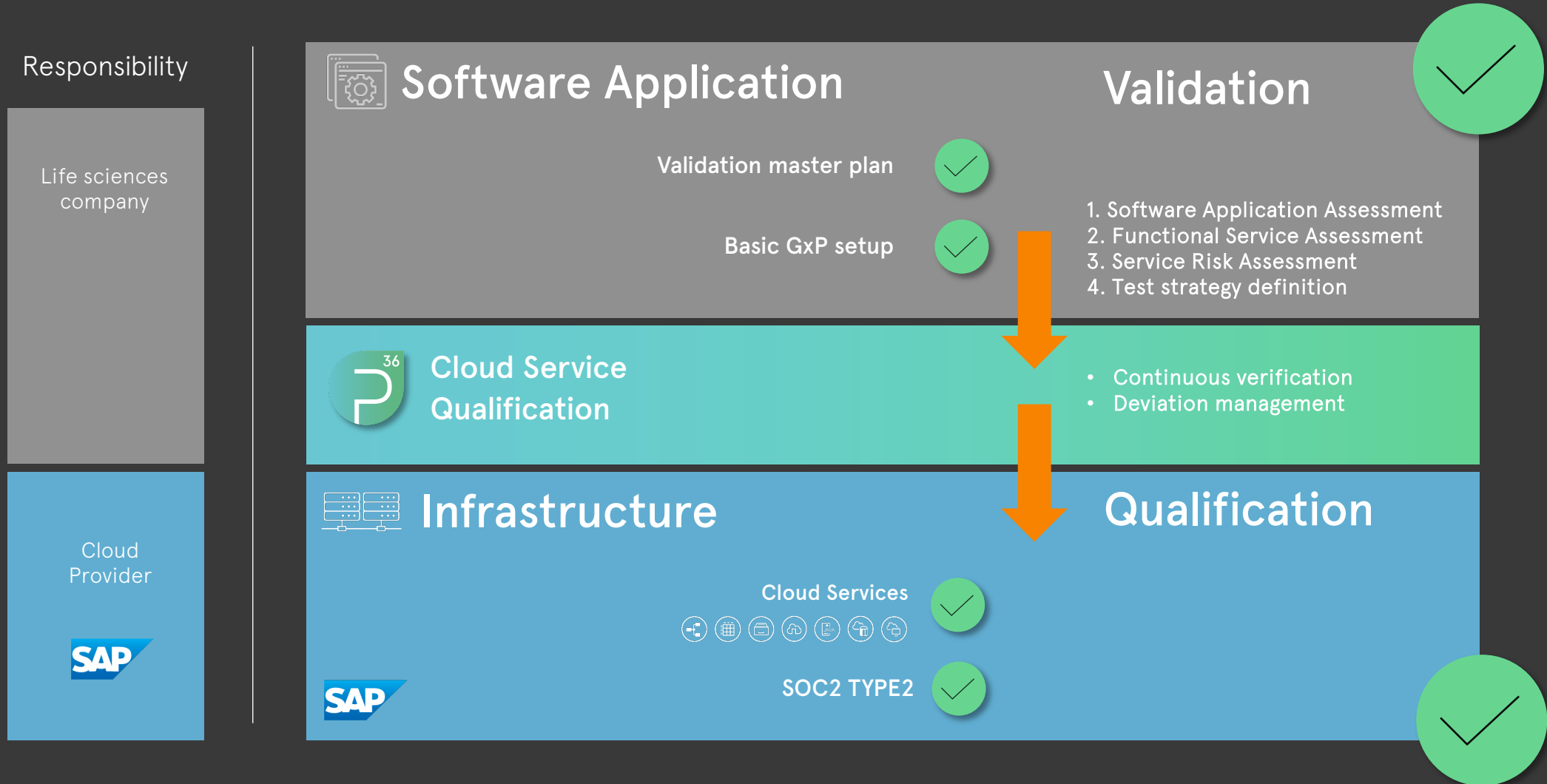
TRADITIONAL COMPUTER SYSTEM VALIDATION & QUALIFICATION



COMPUTER SYSTEM VALIDATION & QUALIFICATION IN CLOUD ENVIRONMENTS



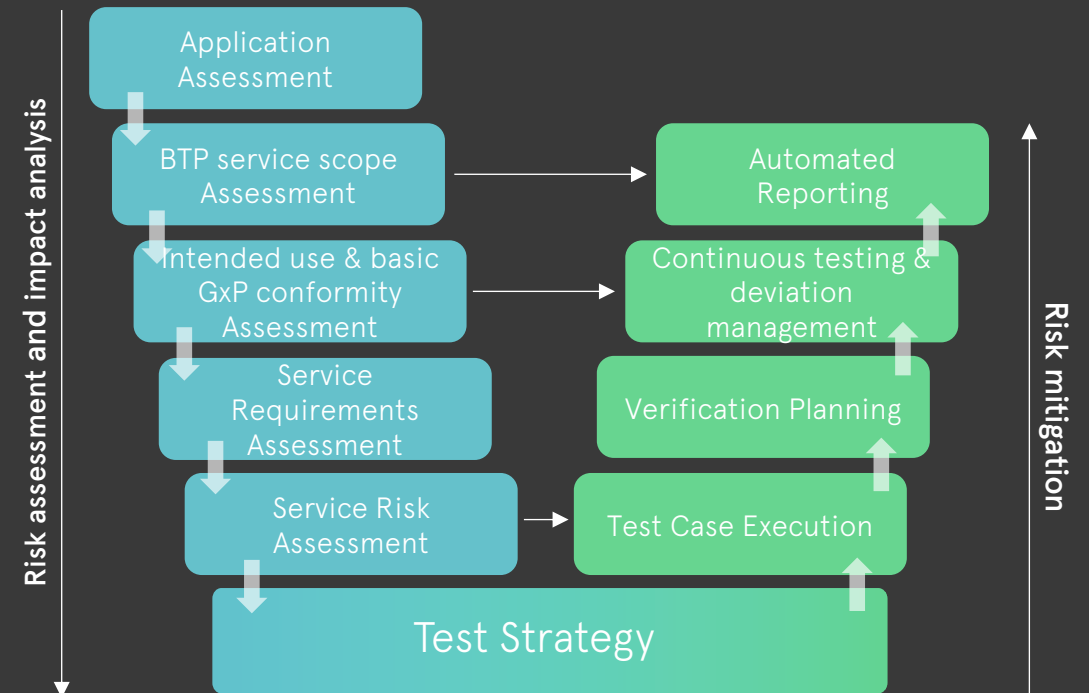
COMPUTER SYSTEM VALIDATION & QUALIFICATION FOR CLOUD ENVIRONMENTS WITH P36



SOLUTION APPROACH SUMMARY

- ◆ Risk-based approach of **Continuous Service Qualification** to create a qualification equivalent for applications on SAP BTP
- ◆ Define intended use/requirements and conduct risk assessment from SaaS application perspective and derive testing strategy
- ◆ **Mitigates risk** of unintended and undetected changes on Platform-as-a-Service level
- ◆ Continuous verification that **intended use** of BTP Services is met and thus validated state of the GxP application is being maintained.
- ◆ Continuously **monitor compliance status** of BTP Services used in application

CLOUD SERVICE QUALIFICATION METHODOLOGY



SERVICE QUALIFICATION PLATFORM FEATURES



Service Qualification Planning

Plan your cloud service qualification based on the assessed application risks



Continuous Test Execution

Test the used services continuously to monitor that all functions are working as defined in the intended use



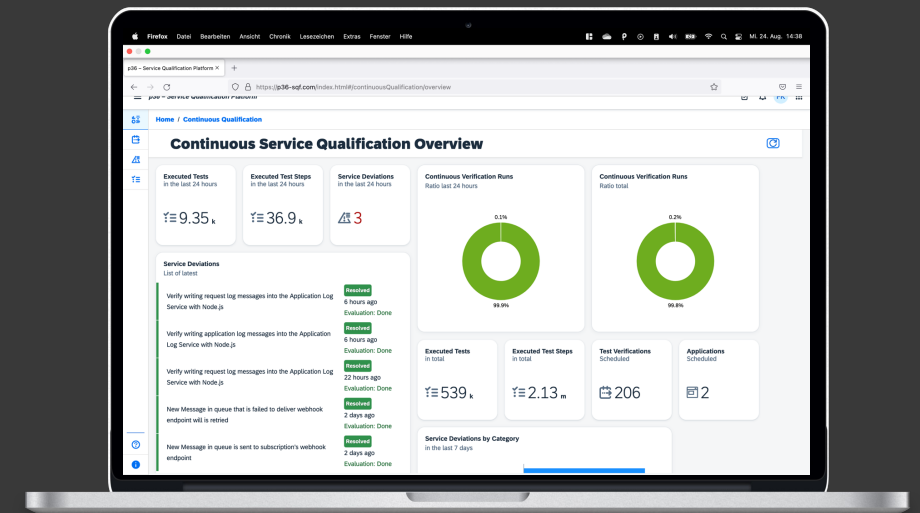
Automated Deviation Handling

Define mitigation strategies for failed tests and automatically execute mitigation processes



Automated Reporting

Create reports based on your continuous qualification to allow a compliant GxP documentation



VALUE OF CLOUD SERVICE QUALIFICATION





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