**Scope Sheet**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Division/Business Unit | PH | CH | AH | C-IT Q | |
| Product Lifecycle Phase | Product Development | | | |
|  | Manufacturing (Sites) | | | |
|  | Commercial Operations | | | |
|  | Shared Service Centers | | | |
| Region/ Country\* | Global | | | |
|  | EU | | | |
|  | US | | | |
|  | Specific country: ………………………. | | | |
|  |  | | | |
| Materials\*\* | APIs (incl. API starting materials, intermediates) | | | |
|  | Non-sterile drug products (incl. bulk and combination products) | | | |
|  | Sterile drug products (incl. bulk and combination products) | | | |
|  | Biotech products | | | |
|  | Medical devices | | | |
|  | Cosmetics | | | |
|  | Ectoparasiticides (non-drug products) | | | |
|  | Food supplements (for human use) | | | |
|  | Medicated feed (non-drug product) | | | |
|  | Veterinary vaccines (non-drug product) | | | |
|  | Other products | | | |
|  |  | | | |
| Relevance for R&D QM | Affected | | | |
|  | Interface | | | |

*\* Manufactured in or for region / country*

*\*\* Regulation applies to each site that handles the materials selected*

|  |  |
| --- | --- |
| **Lead Area:** | Quality |
| **Replaced Document:** | N/A |
| **Global Process Owner:** | Sigrun Seeger |
| **Document Owner:** | Sigrun Seeger |
| **Document Author(s):** | Achim Till Pfeil, Birgitt Liebrecht, Carsten Meyer, Christian Billig, Ruediger Teitscheid, Sigrun Seeger, Ulf Geisler, |

**Related Documents**: SOP 2028 „Manage IT Infrastructure Service Life Cycle”

**Note:** To use this template please open the native content of this document, remove the first two pages and replace the <BLUE> text with your qualification item information. Addition of text, tables and sub-chapters is possible. Text given in black color is binding and is not expected to be changed or removed.

In case this document is signed electronically in a document management system, please also remove the first page and the signature page as this will be generated by the respective system.

History of changes

|  |  |  |
| --- | --- | --- |
| **Version** | **Significant changes with respect to previous version** | **Effective date** |
| 1.0 | New Document | 2019-03-01 |
| 2.0 | - Updated introductory notes  - Aligned format throughout the templates  - Clarified explanations (blue text) in several places | See cover sheet |

**IT Infrastructure Service Qualification Report**

<Bayer site/department/building>

|  |  |
| --- | --- |
| <Describe service name / identifier.> | |
|  | |
| **Related Change Request** | <Change Request No.> |
| **Related Risk Assessment** | <Risk Assessment No.> |
| <Add additional Information, if needed.> |  |

**Signatures**

|  |  |  |
| --- | --- | --- |
| **Author** | **Date:** | **Signature:** |
| <Name>  <Department> |  |  |
| **Review & Approval** | **Date:** | **Signature:** |
| **IT Infrastructure Service Owner**:  <Name>  <Department> |  |  |
| **Quality Assurance**  <Name>  <Department> |  |  |
| <Role>  <Name>  <Department> |  |  |

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# Introduction

## Purpose

This document describes the activities, according to the Qualification Plan < Doc. Reference> that have been carried out to qualify the IT Infrastructure Service <name & identifier>. The qualification results are summarized within this document. Deviations and corresponding measures are described. The approval of this document releases the IT Infrastructure Service for use.

## Scope

<This section describes the scope of the qualification activities in the context of the IT Infrastructure Service, including the organizational scope: Where and for which business case/application/platform is the service to be used? (Also consider the outcome of the impact assessment)>

## Out of Scope

<This section describes the service/service components/features which were out of scope of this qualification:

Define/name the service/service components/features (like processes/systems/applications, etc.) and explain why they were not part of this qualification e.g. listed IT Infrastructure service/service components were part of previous/further qualification(s) (Please reference the respective documents if possible.)>

## Description of the IT Infrastructure Service

<Provide a general short description of the IT Infrastructure Service/ in scope, e.g. based on the description in the IT Infrastructure Service Requirement & Impact Assessment.>

# Summary and Release Decision

<This section should include a summary and assessment of the qualification results. A release statement should be given.>

|  |  |
| --- | --- |
| Qualification successful | ( X ) Yes: no critical system or process errors found. IT Service can be released.  ( ) Yes, but measures needed: no critical system or process errors found. IT Service can be released, but corrective measures required to maintain the qualified state.  ( ) No: Critical system and/or processes errors found, one or more corrective measures required before the service can be released. |
| Conclusion Statement | <Provide a statement of conclusion such as ‘based on the results of this qualification, the IT Infrastructure Service has been maintained in a validated state and has been operating as intended. The gaps identified in this protocol do not have an impact to the qualified state of the .IT Infrastructure Service.> |

# Definitions / Abbreviations

<Refer to a glossary or provide a table with the definitions of the terms used in this qualification.>

|  |  |
| --- | --- |
| **Term** | **Description** |
|  |  |
|  |  |
|  |  |
|  |  |

# Actions

| **Deliverable** | **Result /** Document name, ID, version |
| --- | --- |
| Specified IT Infrastructure Service & qualification scope | |
| Service Description |  |
| IT Infrastructure Service Requirements & Impact Assessment |  |
| Detail qualification activities | |
| Supplier / Service Provider Quality Assessment |  |
| Qualification Plan |  |
| Specified service | |
| IT Infrastructure Service Specification |  |
| Performed fit/gap analysis and Risk Assessment | |
| Risk Assessment |  |
| Testing | |
| Test Plan incl. Test Cases |  |
| Executed Test Cases |  |
| Test Report |  |
| Established manuals and train users | |
| Training Concept |  |
| Established procedures and agreements | |
| Operational Concept |  |
| Roles Concept & Access Rights Management |  |
| Quality Assurance Agreements (QAA) |  |
| Incident & Problem Management |  |
| Deviation Management |  |
| Configuration Management |  |
| Change & Release Management |  |
| Periodic Review |  |
| Release service | |
| Qualification Report | This document |

# Deviations and Resolutions

<Describe deviations that have occurred. The following topics are required for each deviation:

Description: If applicable, refer to a document that is affected

Assessment: Specify criticality

Resolution: Describe how to handle the deviation. Give a planned resolution date, if applicable.

Responsibility: Specify who is responsible for the implementation of the resolution(s)

List of all deviations incl. (corrective) actions:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Deviation ID** | **Description / Cause** | **Assessment** | **Resolution / CAPAs** | **Responsibility** | **Status** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

# Governing Documents

<Add the list of governing documents as applicable, to e.g. relevant SOPs, specifications, instructions.>

| **Document No.** |  | **Title** | **Storage location** |
| --- | --- | --- | --- |
| SOP 2028 |  | Manage IT Infrastructure Service Life Cycle | LifeDoc |

# Referenced Documents

<Add list of documents referenced in the text of this document>

| **Document No.** | **Title** | **Storage location** |
| --- | --- | --- |
| < document number> | < title> | <room or system> |
|  |  |  |

# Appendices

<Add the list of further appendices, as applicable, e.g. test cases, test documents, form sheets, software documentation, sampling plan, etc. that are maintained separately from this document>

| **Appendix No.** | **Document No.** | **Title** | **Storage location** |
| --- | --- | --- | --- |
| <x> | <Doc. No.> | <Title> | <enter room or system> |
|  |  |  |  |
|  |  |  |  |

# Document History

| **Version No.** | **Changes (incl. reason for changes)** | **Effective date** |
| --- | --- | --- |
| <1> | <New version.> | <YYYY-MM-DD> |