**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.

**For use in ValGenesis:**

In case of using the traceability and Risk Assessment functionality within ValGenesis, the information in Section 3 (Requirements tables) needs to be separated out into separate document. Once the tables are read into the traceability and Risk Assessment by the system, they will be modified through change control only and maintained from there in the document itself.

General parts that may need to be versioned via traditional document versioning need to be maintained separately.

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 Specification**

<Bayer site/department/building>

|  |  |
| --- | --- |
| <Describe service name / identifier.> | |
|  | |
| **Related Change Request** | <Change Request No.> |
| **Related Requirement and Impact Assessment** | <Document 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 contains the specification on an infrastructure level for name and identifier of the service/service component or component feature. The following sub-sections specify the service/service components/component features focusing on overall topics e.g. the architecture, environment and dependencies.>

## Assumptions and Dependencies

<Describe external factors that may have an impact on the service but are not described elsewhere in this document.>

# Abbreviations / Definitions

<Refer to a glossary (e.g. GMP/GDP Glossary 200) or provide a listing of specific terms used in the context of this service qualification. Example, see below :>

|  |  |
| --- | --- |
| **Term** | **Description** |
| CI | Configuration Item |
| <term> | <term’s definition> |
| <term> | <term’s definition> |

# Service Specification

<If the sections below should be included into a traceability matrix in ValGenesis, the specifications should be laid down in the format. The “Requirement Reference includes the unique IDs used in the Requirement and Impact Assessment. In this case, as for the Requirement and Impact Assessment, this section 3 should be maintained as a separate document.>

## Service Description

<Provide a general description of the IT Infrastructure Service (component) including the technologies and/or other components the service is composed of. Describe the delimitation of the service and/or components, e.g. what is **not** part of the service? If possible, include a picture with a high-level overview. For what region (scope) does this service apply? Provide a reference to the corresponding Service description>

## Architecture

<Describe the basic structure of the technology applied and the corresponding operating environment. Describe possible variants and specialties. Are there specific Bayer standards to adhere to for setup and operation of the technology? Refer to them by name, ID and location. The use of diagrams and tables is highly recommended.>

## Hardware & Software

<Is the use of hardware/software necessary for the operation of the technology?>

## Interfaces & Dependencies

<Outline the interfaces of the service to other services, platforms and applications. What technical interfaces to other components are used for operating this technology? Also describe which external parties (supplier/provider) are contracted to provide (components of) the service.>

## Overview of Data Landscape

<What data is kept / for whom and where? Describe how specific requirements for data storage (e.g. EU, data privacy requirements) are addressed. Distinguish user data and operational data that is necessary for the operation of the technology. How do you administer your own data sources and where are they located? Define retention period of data and documentation.>

## Fail-safety and service availability concept

<What are the minimum requirements for fail safety and availability of the service? What basic concepts are there to ensure fail safety and availability? Describe the supported measures to assure the service availability needed?>

# 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 |
| <Doc. No.> | <Title> | <enter room or system> |

# Referenced Documents

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

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

# Document History

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