# Purpose

This SOP describes the procedure of change request submittal and processing into SAP ERP, roles of the process participants and allocation of responsibilities between them.

Scope

This document covers:

* + The process of doing and processing change requests into SAP ERP;
  + The procedure of control of performing the change request.

This document doesn’t cover:

* + process of incident handling in SAP ERP system;
  + functioning and support of other information systems and applications;
  + the procedure of object transport and development in SAP ERP system;
  + administration of user access to the SAP ERP system;
  + changes to the data wizard in SAP ERP;
  + methodology of project management in the company.

**Definitions and abbreviations**

**IMS (information system)** is a scope of program decisions designed for automotization of the company’s business-processes.

A change (in IMS) is an event which is not an error, and related to modification of any IMS functionality caused by changes of legislative requirements and local standard rules and the company’s policies.

A change request is a formalized document reflecting the changes in the framework of IMS.

An incident is any event which occurred within the maintenance, and is not a component of normal IMS functioning which entails, or may entail cessation of user’s work in IMS, or loss of quality of his/her work.

Service request is an application for performing a standard operation in the system, and not accessible to a user within his powers, and not related to the changes of IMS functional.

(Technical) support service is a service designed to provide support to the company employees (ISIT Service Desk).

**GxP** is an abbreviation meaning the rules of proper performance practice of processes at different stages of a medication life cycle (development, testing, production, distribution and selling), containing the requirements to critical aspects of processes designed to insure quality of medications.

**SoD** is an abbreviation which means the rules of the distribution of authority.

A project is an organized sequence of actions caused by the need to do significant changes to one or several IMS in accordance with the agreed business-case.

IMS user is any employee of the company who has an authorized access to SAP ERP system to process operations according to his/her business-functions.

Key IMS user is a user of SAP ERP system who has extended powers in IMS and/or special knowledge in the framework of his/her business-functions.

**Project (request) portfolio (task register**) is a list of current and upcoming developments in IMS, with the indication of the responsible initiator of the change, the due dates, urgency and priority, as well as the current performance status.

## Responsibility Allocation

Change Initiator

Potentially, any company employee may be a change initiator. The change may be caused by the current business requirements of the company or the subsidiary, by changes in the local procedures or regulatory legislation.

In this event, only a part of the upcoming changes may be related to the change in SAP ERP.

The change request initiator is responsible for the following functions:

- formalizes the upcoming changes in the scope sufficient for technical and economical basis;

- initiates the agreement of the change request with the involved business subdivisions and structures;

-is responsible for the realization of the changes which are not connected with changes in SAP ERP (including methodological and organizational assistance);

- assigns responsible initiator of change request in SAP ERP;

-accepts the works on the changes realized on the side of SAP ERP by the responsible initiator;

- Change request initiator may perform the role of the responsible change request initiator in SAP ERP (see p. 4.2).

## Responsible change request initiator in SAP ERP

Any system user SAP ERP system who has sufficient knowledge and experience of working with SAP ERP system as a user may be initiator of changes in the system.

Initiator of SAP ERP change request is responsible for the following tasks in the framework of realization of the change request:

- Initiation of the change request in SAP ERP;

- technical and economical basis of the change request development (if necessary);

- specifying the circle of persons potentially interested in the change realization and their informing (agreement, involvement, etc.);

- agreement of functional scope of the change request with the line manager and/or Steering committee;

- agreement of the functional scope of the change request with the user of the similar functional of SAP ERP system in the region;

- agreement of the overpatching scope with the owners of the systems and local person in charge of GxP;

- requests the necessary resources from the line manager and/or Steering committee, to be included in the working group or project team;

- testing of the development under his account at the test landscape;

- takes a decision on the development compliance with the starting requirements;

- peer review and support of the realized change in the productive system;

- keeping the documents in the relevant state (operational instruction, SOP, etc.);

-update of the documentation after the change request realization;

- agreement of the distribution on the results of the change request development;

- communication with consultants-developers from the project team to clarify the initial requirements of the development and provision of the test data and samples;

-organizational communication within the company which is not directly connected with realization SAP change, but necessary in view of the change realization;

- provides formal description of the business process, affected by the change, in case of a new business process, or on the request of the project team within the change request realization;

- Confirms with SoD and/or GxP persons, addition of transactions in the role;

- informs the change initiator of the results of the change request realization in SAP ERP.

He/she may be delegated as a project manager if the change is classified as a project.

Change management specialist

SAP ERP change request specialist is an employee of IS\IT department.

SAP ERP change request specialist shall be responsible for the following tasks in the framework of the change request realization:

- provisional technical expertise of the prospective decision and/or its request from the project team, if required, through the support service;

- training and assessment of the end users and business departments experts, the procedure of SAP ERP change management;

- control and maintenance of the SAP ERP changes procedure within the company;

- organization and assistance in testing on the realized change;

- coordination of the work of consultant-developer project team on the change realization;

- distribution of the changes on the SAP ERP change process;

- open request logs and their statuses analysis;

-control of change request performance according to the current procedure (see p. 5.9);

- change request fixation and its current statuses in the open request register of IS\IT department;

- collection of SAP ERP change initiatives for change portfolio planning;

- informational distribution of the upcoming SAP ERP changes;

- collection and realization of proposals on the information support of SAP ERP change procedure;

- indication of the necessity to prioritize open change requests for line managers and/or Steering committee (from portfolio manager role);

- periodical provision of the Steering committee with the status on all the open and closed change requests (in SAP Steering Committee format);

- support of local business expert database (see Annex 1);

May be delegated for the role of the project manager if the change is classified as a project.

Business expert

Business expert is an employee of any department who is provided with relevant powers and has necessary experience and knowledge in SAP ERP system, including experience of change realization and project management.

Business expert is responsible for the following tasks in the framework of change request realization:

- agreement of the change request functional scope from the direction of the change initiator;

- agreement of the change request functional scope with the similar functional user in SAP ERP system in the region;

- peer review and basis of necessity to perform the suggested change request;

- allocation and agreement of the working group staff for the agreed change realization;

-organizational communication within the company which is not directly connected with the SAP change realization but necessary in view of the change realization.

He/she may be delegated for the role of project manager if the change is classified as a project.

Steering committee

Steering Committee is the group of business experts, allocated company employees who have relevant knowledge, experience and powers.

Steering committee and its members shall be responsible for the following tasks in the frame work of change request realization procedure:

- allocation and agreement of the resources which are necessary for positioning and testing the change request;

- insuring necessary communication at the department level within the framework of its functional area;

- agreement of the project team members;

- taking decisions on SAP ERP change process organization process;

- taking decisions on prioritization of the current requests;

- addition of the new employees to the Steering committee.

It is possible to invite participants to the Steering committee, depending on the agenda and the realized changes.

First line of the support service

First line support service personnel shall register and classify the request according to the global procedure.

See Service Level Agreement Corporate SAP ERP SLA.6 and SOP CF-SAP-07 Change control for SAP system.

Second and third line of the support service

Second and third line support service personnel shall assess and conduct the development on the request according to the global procedure.

See Service Level Agreement Corporate SAP ERP SLA.6 and SOP CF-SAP-07 Change control for SAP system.

# Procedure performance

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| --- | --- | --- |
| No. | **Responsible executive** | **Procedure/Action** |
| 5.1 | Change request initiator | Change initiation (See SOP-QA-L-RU-06 v.02) |
| 5.2 | Responsible SAP ERP change request initiator | SAP ERP change request initiation |
| 5.3 | Change management specialist | Indication of the necessity of project-change portfolio on SAP ERP  Change request agreement |
| 5.4 | Change management specialist (portfolio manager)  Business experts  Responsible SAP ERP change request initiator | SAP ERP change request agreement |
| 5.5 | Responsible SAP ERP change request initiator | Submission to the support service |
| 5.6 | Support service, 1st line | Registration and assigning the executive group |
| 5.7 | Support service, 2nd line | Assigning the performer and agreement of the resources and dates |
| 5.8 | Support service  2nd and 3rd line | Development on the request and the duty test of the request |
| 5.9 | Responsible SAP ERP change request initiator | Testing and confirmation of the development transference |
| 5.10 | Support service, 2nd and 3rd lines | Transference of the development and technical documentation update |
| 5.11 | Responsible SAP ERP change request initiator | Update of operational documentation |
| 5.12 | Responsible SAP ERP change request initiator | Distribution of the realized changes |
| 5.13 | Change management specialist (portfolio manager) | Request performance control, request portfolio actualization by the results of realization |
| 5.14 | Responsible SAP ERP change request initiator | Informing the change initiator (p.5.1) of the results of the change realization. |

Change Initiation

Change request may be initiated by any company employee in either business area on the basis of the change of local business processes, external requirements to the company, innovative processes realization, etc.

See SOP-QA-L-RU-06 v.02 Change management system.

If the change covers other information systems except for SAP ERP, the change shall be drawn and realized as a project.

The responsible initiator may be the change initiator himself, or be delegated by the Steering committee.

## SAP ERP change request initiation

SAP ERP change request initiation shall be launched at the positive decision on the change agreement (see p.5.1), or in other local changes in the company procedures, which are reflected in SAP ERP IMS.

SAP ERP change request shall be initiated by the responsible initiator of the change.

The responsible initiator shall formulate the request according to the requirements of p.5.2.1, and submit it via e-mail to the change management specialist and the business expert for agreement (See Annex 1).

The agreement of the request by the change management specialist and business experts shall take place simultaneously within 5 business days.

### General requirements to the contents of SAP ERP change request

SAP ERP change request shall contain the following information:

1. Short name of the change which conveys the essence of the necessary changes;

2. Basis:

* Reference to a change in the legislation;
* Reference to the methodological guidance and and/or local SOP which are already effective or coming into force;
* Reference to the change in the adjoining system which affect SAP ERP;
* The user’s own formulation;

3. Desirable due dates in the form of a precise date or a period (for instance, closure period, fiscal year).

4. Request relevance:

* Absence of this functionality makes it impossible to perform business operations- there is no bypass solution;
* Absence of this functionality does not prevent the system from working- there is a temporary solution;
* Addition of this request will extend the options of the system.

5. Detailed description of the new SAP ERP change:

* If the realized change results in the new report in the system, the request must contain the information on the margins on the selection screen and data output screen.
* If the realized change results in an uploading/downloading file, the request must contain the file template in the format supported by the system.

7. The test case in productive or testing system which indicates:

- transaction name, the report, the program;

- SAP document numbers.

8. Related change requests and incidents.

The information on the change request shall be submitted, in the specified form, by the request initiator for agreement with the business expert and the change management specialist.

Expertise request

If there is a lack of information on the current realization, system setting and options, the responsible change request initiator is enabled to create an expertise request.

An expertise request may be opened both by the responsible initiator, and the change management specialist.

In the expertise request, it is necessary to indicate the functional area and the module on which consultation is required.

In the request copy, it is also necessary to specify the line manager, business expert and potential performer if available.

Such request shall be classified as a service request.

After the expertise request is closed, the initiator, on the basis of the provided expertise, will open the new request- on realization, through submission to the support service (see P. 5.2.1).

Urgent change requests

In performing urgent change requests, the stages of technical and operational documentation update may be postponed until the moment after completion of the development and transference, as well as the stage of formal agreement with the steering committee.

Realization of the urgent request takes place, in view of necessity, through prioritization of the current requests (see p. 4.5 Steering committee).

Prioritization of urgent requests among the 2nd and 3rd support line personnel shall be processed by the support service manager initiated by the change management specialist.

Rise of the request priority shall be processed through submission to the 1st line of the Support Service.

## Reflection of the request in the change portfolio and agreement

Reflection of the necessity in the change portfolio

Change management specialist shall fix a change request in the IMS change portfolio.

The change necessity shall be fixed indicating the short name of the change, initiator’s full name, function, provisional dates, priority and current status, as well as the reason for the refusal if applicable.

The change portfolio is available in the view mode for the business experts and IMS key users.

Both coordinated, and uncoordinated necessity of SAP ERP change shall be fixed.

Analysis of the changes in the portfolio (information updates) shall be made by the change management specialist (portfolio manager) periodically, and according to change coming and realization.

### Request agreement.

Change management specialist shall agree the request and control observing formal requirements to the SAP ERP change request initiation according to p. 5.2.1.

If there are project criteria in the request, it shall be reported to the responsible request initiator and business experts the necessity to draw it up as a project.

## Agreement of SAP ERP change request by business experts

The SAP ERP change request shall be submitted to the business expert for agreement via e-mail.

If the prospective SAP ERP changes affect similar processes for the users of the branch offices, a business expert or a line manager shall submit the request to the manager of the corresponding branch office.

In case of positive decision of the branch office employee, the business expert or line manager shall take a decision to agree the change request and build up the project group to perform it and/or assign responsible initiator

In case of negative decision of the branch office, the decision on the change realization and its scope shall be taken at the upcoming Steering committee.

In case of line manager’s positive decision, the change request shall be submitted by the request initiator to the Support Service address, and the change management specialist shall fix the task in the register of opened requests.

In case of line manager’s negative decision, the change request shall be fixed by the change management specialist in the register of opened requests with ‘Idea’ status

The line manager or business expert shall provide the formal reason of change realization refusal.

The agreement date shall account for 5 business days.

Creation of the address to Support Service

After the change request (p.5.4) is agreed with the business expert and change management specialist, the responsible request initiator shall submit the request to the Support Service Address:

Service Desk [ISITServicedesk@takeda.com](mailto:ISITServicedesk@takeda.com)

The request shall be compiled in Russian and translated into English, or only in English.

In the copy of the message to the Support service to indicate:

- change management specialist

- business expert or line manager

- prospective performer from Support Service (see p. 5.2.2 Expertise request)

The subject of the message shall be filled according to SAP ERP module.

Registration and assignation of the executive group

The step of the procedure shall be processed according to SOP CF-SAP-07 Change control for SAP system and Service Level Agreement Corporate SAP ERP SLA.6.

## Assignation of the performer and agreement of dates and resources

The step of the procedure shall be processed according to SOP CF-SAP-07 Change control for SAP system and Service Level Agreement Corporate SAP ERP SLA.6.

Assignation of the performer upon request shall be processed by the responsible administrator of Support Service group.

The performer shall put the provisional date of the change realization, the date of its delivery in the test environment and informs the responsible change request initiator via e-mail.

## Development on the request and operating test of the request

The step of the procedure shall be processed according to SOP CF-SAP-08 Testing and Qualification of SAP system.

Testing and confirmation of the development transference

A Support Service Employee shall inform the responsible initiator that the realized request is ready for testing.

Testing of the request shall be processed by the responsible change request initiator. The testing takes place at the test landscape in SAP ERP system (QAS, CUS) under users’ own accounts.

If more than one user is required for testing, the initiator, through the line manager or business expert, shall involve a new user into the working group.

The test shall be processed on the testing data which are available in the system, provided by the request initiator or a Support Service Employee.

Document support of the testing (sequence of steps, starting instructions, etc., shall be processed by the Support Service employee.

Upon testing completion, if it is not agreed additionally, no formal documents are required (protocol, scenario, etc.).

Development transference and technical documentation update

The step of the procedure shall be processed according to SOP CF-SAP-08 Testing and Qualification of SAP system.

Transference of the realized changes shall be processed by a Support Service employee on the basis of e-mail confirmation from the responsible request initiator that the testing has been completed successfully.

Technical documentation update shall be processed by a Support Service employee in the project folder. Operating testing instructions are not saved.

Operating documentation update

Operating documentation update shall be processed by the responsible SAP ERP change initiator or business expert in this area.

After the developments on the requests are completed, their responsible initiator shall update or prepare operating instruction of SAP ERP user on the realized changes. If necessary, the change request initiator does the relevant changes to SOP which describes the changed process beyond the SAP ERP system.

Prepared or updated operating instruction for SAP end user shall be placed by the request initiator at general corporative depository for SAP-documentation in the regular version to ‘User’s operating instructions’ section

Distribution of realized changes

After the realized changes are transferred to the productive landscape, and the documentation is updated, the end SAP users shall be informed of the realized changes through distribution.

The distribution shall be processed by the change request initiator or SAP ERP changes specialist, upon the agreement with the initiator and/or line manager.

The newsletter shall consist of:

-Name of the module, subsystem, integration unit of SAP ERP system in whose framework the changes were realized;

-Name of transaction, report, development;

- Short description of the realized functionality and its options (realization purpose);

- Reference to the documentation (SOP, user instruction);

- Contacts of the change request initiator (to provide expert support of the realized change for the end users);

- Names of rights and power objects (role, transaction, name of report, if started through /n/PSB/sa38) required for the access.

Distribution of the realized changes shall be processed via MS Outlook mail to the following groups of SAP users

Cco.dl.RU-SAP-Users-RU [Cco.dl.RU-SAP-Users-RU@takeda.com](mailto:Cco.dl.RU-SAP-Users-RU@takeda.com)

Cco.dl.RU-SAP-Users-RU-YV [Cco.dl.RU-SAP-Users-RU-YV@takeda.com](mailto:Cco.dl.RU-SAP-Users-RU-YV@takeda.com),

If the realized changes are global in character and affect all the SAP users.

If the realized changes are local in character and affect SAP users of particular subsidiary, the distribution shall be processed to the groups assigned to corresponding subsidiaries and their branch offices.

Control of the procedure performance

Control of performing the SAP ERP realization requests shall be processed through project portfolio support by change management specialist from IS\IT department.

Change management specialist shall give a report on the request realization process at the Steering committee, as well as when addressed on the status of particular SAP ERP change request.

Current control of the status of change request performing shall be processed by the change management specialist periodically or upon request from the responsible initiator, or the Steering committee via **CS-esmile system** (consequently, integrated service **ServiceNow**).

Authorized access to the system of storage and application processing in the framework of the procedure shall be granted only to the change management specialist.

Informing the change initiator

Upon completion of the request realization and the documentation update, responsible change request initiator shall inform the change initiator of the results of the SAP ERP change request realization in the framework of the change.