Title: **RA for Customer Batch Reservation**

Document ID: **R05_RA_O2C_CBR_All_V1.0**

Document Type: **Risk Analysis RA**

Organization: **Pharma Group Germany**

Implementation Reference: **Rollout Project R5**

Solution Reference: **SAP ERP 6, System P01**

Business Process Master List Assignment:

Business Scenario: **Order-to-Cash O2C**

Business Process: **Customer Batch Reservation**

Sub Processes: **Reservation Creation**
Reservation Call-Off
Reservation Cancellation
Reservation Reporting

Version: **1.0**

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Document Responsibilities

	Responsible Person [Name, CMG]	**Date/Signature** [dd-mmm-yyyy]
Edition		
Review		
Approval		

History of Changes

Version	Version Date	Changes compared to previous version
1.0	20.10.2012	Creation of first version

Table of Contents

1 Objectives and Scope of Document

This document describes the GxP-related risks (Product Quality, Patient Safety) that are associated with the implementation of the requirements of Pharma Group Germany for the single steps in the business process “Customer Batch Reservation”.

2 Risk Assessment

Risk ID	UR-ID	Description of Sub Process / Activity	Trans-action	Transaction Name	Description of GxP Risk	Risk Root Cause	Risk Rating > Low > Medium > High	Risk Reme-diation Ref. ID	Comments
RI1235	1235	Reservation Creation	VA01, VA02	Enter / Change Customer Order	The wrong batch is selected for reservation creation	Communication Error / Data Entry Error	Low	1	
RI1239	1239	Reservation Call-off	VA01, VA02	Enter / Change Customer Order	The wrong batch number is displayed for selection	IT System Malfunction	Low	2	
RI1241	1241	Reservation Cancellation	VA01, VA02	Enter / Change Customer Order	Quality Check not done although requested	Insufficient Process Control	Low	3	
RI1243	1243	Reservation Reporting	ABAP Report	ABAP Report	Batches may expire before called off	Insufficient Information in Report	Low	4	

3 Remediation Plan

Risk Remediation Ref. ID	Description how Risk will be mitigated	Mitigation Category	Resulting Requirements for the FRS		Resulting Requirements for Testing	
			Description	Reference to corresponding Document	Description	Reference to corresponding Document
1	Customer is asked to send product / batch numbers that shall be reserved in a written form	Organisational Solution	n.a.	n.a.	Test step needed where a batch number is entered manually	To be completed before Testing
2	Definition of specific test cases	Test	Description how this functionality will be implemented (Standard or Enhancement)	To be completed after FRS creation	Tests must cover all combinations of Customer / Product reservations (m:n relationship)	To be completed before Testing
3	Definition of rules when a quality inspection is needed, added to SOP “Quality Inspection”	Organisational Solution	n.a.	n.a.	n.a.	n.a.
4	Information about date of last call-off for each reserved batch should be added in report to better assess if remaining quantity will most likely be called off before expiry date of batches are reached	Functional Enhancement	Add this information in report specification in FRS	To be completed after FRS creation	Definition of test cases for new report	To be completed before Testing

4 Appendix

Risk ID	UR-ID	Description of Sub Process / Activity	Trans-action	Transaction Name	Description of GxP Risk	Risk Root Cause	Risk Rating > Low > Medium > High	Risk Remediation Ref. ID	Comments
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)

(1): Unique ID of the Risk
(2): Link to User Requirement (can be Blank if additional Risk is identified that is not mentioned in URS)
(3): Description of the Sub-Process / Activity risk refers to
(4): System transaction used for Sub-Process / Activity
(5): Name of System transaction used for Sub-Process / Activity
(6): Description of the nature of the GxP risk
(7): Description of the root cause of the risk, used to identify possible risk mitigations
(8): Rating of risk (including risk likelihood, risk impact and risk detectability)
(9): Unique ID of the Mitigation proposed for the Risk (Link to next Table)
(10): Comments

Risk Remediation Ref. ID (1)	Description how Risk will be mitigated (2)	Mitigation Category (3)	Resulting Requirements for the FRS (4)		Resulting Requirements for Testing (7)	
			Description (5)	Reference to corresponding Document (6)	Description (8)	Reference to corresponding Document (9)

(1): Unique ID of the Mitigation proposed for the Risk
(2): Description of the mitigation approach for this risk
(3): Category of the risk mitigation
(4): Impacts of the proposed risk mitigation on the FRS (4,5,6 will be reviewed after FRS has been created)
(5): Description of what needs to be included in FRS
(6): Link to FRS (Functional Requirement, will be added after FRS has been created)
(7): Impacts of the proposed risk mitigation on the Test (7,8,9 will be reviewed after Tests have been defined)
(8): Description of what needs to be included in Test Cases
(9): Link to Test Cases (will be added after Test Cases have been created)