
	Auditing of ABX	
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SASAI Audit agenda

Audited Company: ABX advanced biochemical compounds GmbH Radeberg

Audit Team
Dr. Rainer Suchi (Lead Auditor)
Prof. Marianne Patt (Subject Matter Expert)

Date of audit:	Time:	Location:
19.04.2023	8.30 am – 6 pm	Radeberg (Germany)
Subject:		
General quality system and product audit against EU GMP VOL IV part II (API) and EU GMP VOL IV – Annex 3 (Manufacture of radiopharmaceuticals)		
Goal:		
Re-qualification as supplier of APIs, reagents and hardware kits		
Required Documents:		
List of SOPs; organisation chart; plant layout; current certificates; site master file		

TOP	Topic	Description	Responsible	Time
1.	Introduction	<ul style="list-style-type: none"> • Explanation of goal, scope, and applicable standards of the audit • Introduction of auditor and staff members accompanying the auditor • Company presentation and product workflow • Co-ordination of audit program and timeline • Major changes since the 2019 audit 	Audit Team / ABX	8:30 – 10 am
2.	Facility Tour	<ul style="list-style-type: none"> • Goods receipt area • Production • Quality Control • Packaging • Dispatch • Warehouse 	Audit Team / ABX	10 am – 1 pm
3.	Lunch		Audit Team + ABX	1 – 1.30 pm

4.	Quality system	<ul style="list-style-type: none"> Management review, training, self-inspection, documentation control, complaints/deviation, CAPA, change control, recalls, risk management, validation & qualification programme, maintenance, calibration schedule, cleaning, pest control, data integrity release process, supplier management. <p>The focus will be on changes of the quality system since the 2019 audit and recent examples for the ongoing application of the quality system.</p> <ul style="list-style-type: none"> Follow-up of CAPAs from 2019 audit Product-specific documents: batch manufacturing and QC protocols, PQRs for O-18 water 	RS / ABX	1:30 – 5 pm
5.	Product audit	<ul style="list-style-type: none"> Product-specific documents: batch manufacturing and QC protocols, PQRs <ul style="list-style-type: none"> Cassette for synthesis of ⁶⁸Ga-labelled peptides (ABX product no: GA-01-H) Precursor for [⁶⁸Ga]Ga-DOTATOC: DOTATOC acetate (ABX product no: 9702) Reagent set for synthesis of [¹⁸F]F-PSMA-1007 (ABX product no: PS-101) sterile evacuated vials 	MP / ABX	1:30 – 5 pm
6.	Auditor time	<ul style="list-style-type: none"> Internal wrap-up of the auditors 	Audit Team	5 – 5:30 pm
7.	Final discussion	<ul style="list-style-type: none"> Summary of observations Resume of the Audit Next steps (Audit report follow-up) 	Audit Team + ABX	5:30 – 6 pm

Date:

29.03.2023

Signature (Lead Auditor):

