SASAI Audit report

Audited Company	CUP Laboratorien Dr. Freitag GmbH (hereinafter CUP)
Date	31. Aug 2022 - 01. Sep 2022
Reason for audit	Initial qualification as a supplier of analytical services
Subject Matter Expert: **Dr. Phillip Ringel**	Date: Signature
Lead auditor **Dr. Rainer Suchi**	Date: Signature:
Approval: **EANM Scientific Liaison Officer** **Prof. Michael Lassmann**	
Date of approval (DD. MM. YYYY)	

Content

1. Introduction

1.1 Description of the company

CUP was founded in 2006. Already in 1991, the predecessor “Chemical laboratory for environmental and product analysis” was founded. CUP is a family-owned company. They provide services in the field of microbiological, chemical, and physical analysis for pharmaceuticals and medical devices.
CUP holds a GMP certificate covering the quality control of drugs, active pharmaceutical ingredients, and excipients used for humans, animals, and clinical trials. They are regularly inspected by the Saxonian authority and the FDA.
CUP is holding a certificate for compliance with DIN/EN/ISO/IEC 17025:2018 for the testing of medical devices.
Since 2020, CUP is licensed for the sterility testing of “hot” radiopharmaceuticals. This testing is performed in a separate building, licensed for the handling of radioactive samples.

In 2022, the existing laboratory capacities at Radeberg, Germany, were enlarged with a new, state-of-the-art, laboratory building.
CUP employs about 60 people and is working one shift.

The management system of CUP is oriented at the EFQM model. This is a management model encompassing the charter of the basic rights of the European Union, the European human rights convention, the European social charter as well as the United Nations ten principles for sustainable and socially responsible management, and the 17 sustainable development goals.

1.2 Auditor(s)

Lead auditor:

- Dr. Rainer Suchi
  Qualification: > 30 years’ experience as quality assurance and quality control manager of a radiopharmaceutical company; qualified person; certified auditor; > 100 audits (GMP; GDP; Medical devices) as lead auditor

Subject matter expert:

- Dr. Phillip Ringel
  Qualification: Ph.D. in biochemistry and microbiology; hygiene officer and qualified person in an industrial radiopharmaceutical manufacturing company, trained auditor

1.3 Persons met during the audit:

1.4 Regulations & Guidelines used as basis:

- EU GMP guideline part I

1.5 Acknowledgment:

The auditors wish to thank all involved persons for their open and cooperative attitude during the performance of the audit.

2. Observations and deviations

2.1 Facility tour
2.1.1 Sample receipt area
2.1.2 Microbiological laboratory
2.1.3 Analytical laboratories

2.2 Audited quality systems:

2.2.1 Company structure/org chart (Site Master File)
2.2.2 Review of relevant licences
2.2.3 Date and result of last regulatory inspection
2.2.4 Document management system
2.2.5 Training
2.2.6 Deviation handling
2.2.7 OOS handling
2.2.8 CAPA process
2.2.9 Complaint management process
2.2.10 Recalls handling
2.2.11 Change control process
2.2.12 Release process
2.2.13 Risk management
2.2.14 Data Integrity policy
2.2.15 Self-inspection program
2.2.16 Validation and qualification program
2.2.17 Maintenance/calibration program
2.2.18 Hygiene programme & Pest control
2.2.19 Supplier management and contracted services

2.3 Audited departments/processes:

2.3.1 Microbiology

2.3.1.1 Clean room concept (validation, control) & environmental monitoring program
2.3.1.2 Sterility testing of radioactive and non-radioactive samples
2.3.1.3 Bacterial endotoxin testing
2.3.1.4 Microbial enumeration testing & Testing for specified micro-organisms
2.3.1.5 Testing of efficacy of antimicrobial preservation

2.3.2 Physical/chemical laboratories

2.3.2.1 Spectrometry and spectrophotometry (AAS, UV-VIS, IR, ICP-MS)

2.3.2.2 Chromatography (HPLC, GC, IC)

2.3.2.3 Elemental analysis (C, H, N, S) – net peptide content

2.3.2.4 Development and validation of analytical methods

2.3.2.5 Leachables & Extractables analysis of cassettes and vials.

2.4 Deviations

2.4.1 Classification of detected deviations

Critical: The observed condition will seriously affect the quality of the product, violate essential GMP requirements and Quality Assurance practices, or affect regulatory compliance. These observations require immediate action, e.g. stop production, product quarantine, etc.

Major: The condition may affect the quality of the product. The observation documents a clear non-compliance with the GMP requirements and quality assurance practices. An action to be taken with a high priority is recommended.

Minor: This may not necessarily affect the quality of the product, but the condition violates GMP requirements. Actions should be taken within a reasonable timeframe.

Recommendation: These issues are not GMP violations and should be regarded as supportive for further improvements. They are recommendations made by the auditor for improvements to a process/ system.

2.4.2 Critical

2.4.3 Major

2.4.4 Minor

2.4.5 Recommendations

3. Summary