## Supplier Audit

TO: ImCare - [redacted] (R&D), [redacted] (R&D),
AMS Supplier - [redacted] (VP QA/RA), [redacted] (Director of Quality)

| Section | Subject | Response |
|---|---|---|
| 1 | Name/Site/Affiliate | Argonaut Manufacturing Services (AMS) |
| | Location | Street Address: [redacted]<br>State/Province: CA<br>Postal Code: 92010<br>Country: USA<br><br>Address for Purchase Orders [redacted]<br>State/Province: CA<br>Postal Code: 92008<br>Country: USA<br>☒ Onsite Audit ☐ Remote Audit |
| | ISO Standards in Scope | ☐ Not Included |
| | ISO Standards in Scope (Check all that apply) | ☐ ISO 9001:2015 ☒ ISO 13485:2016 ☐ ISO 17025:2016<br>☐ ISO 27001:2022 ☒ ISO 14971:2019 ☐ Other: _____ |
| **Regulations in Scope**<br>☒ Included (complete Section 2) ☐ Not Included (do not complete Section 2) | | |
| 2 | Region/Country-specific regulations | ☐ EU MDD ☐ Brazil ☐ China<br>☐ Canada ☐ Australia ☒ US<br>☐ Korea ☐ Malaysia ☐ Other: _____<br>☐ Mexico ☐ Japan |
| | (Complete if US is included) US FDA 21 CFR Parts | ☒ 11 ☒ 809 ☐ Other: _____<br>☒ 801 ☒ 820<br>☒ 803<br>☒ 806 |

The purpose of this audit report is to verify that the above stated auditee/site underwent a supplier audit on the following date: May 28, 2025. The audit was conducted to the external standards and regulations requirements in the table above and as per Attachment A: Audit Agenda and Attendees.

Sincerely,

[redacted]

# Table of Contents

## 1.0 Audit Details

| Topic/Description | Response | | | |
|---|---|---|---|---|
| **Type of Audit** | Supplier | | | |
| **Site Name/Affiliate/Process/Product** | Argonaut Manufacturing Services | | | |
| **Location** | [redacted]<br>State/Province: CA<br>Postal Code: 92010<br>Country: USA<br><br>Address for Purchase Orders<br>[redacted]<br>State/Province: CA<br>Postal Code: 92008<br>Country: USA | | | |
| **Audit Host** | [redacted] (VP QA/RA),<br>[redacted] (Director of Quality) | | | |
| **Auditors** | [redacted] (Lead Auditor)<br>Hemal Kurani (Co-Auditor) | | | |
| **Date(s) of Audit** | May 28, 2025 | | | |
| **Date of Closing** | May 28, 2025 | | | |
| **Date of Report Issuance** | May 31, 2025 | | | |
| **Number of Observations** | **Critical** | **Major** | **Minor** | **Recommendation/ OFI** |
| | 0 | 0 | 3 | 7 |
| **Date of Critical & Major Nonconformity Notification (if applicable)** | N/A | | | |

## 2.0 Executive Summary

The purpose of this audit is to assess the adequacy, effectiveness, and compliance of AMS Quality Management System (QMS) against ImCare Biotech specific requirements and supplier evaluation criteria for the Seravue Kit LC-SPIK.

**Company Overview**

Argonaut is Contract Manufacturing Organization (CMO) for:

- In-Vitro Diagnostics (IVD) and Life Science Kits
- Aseptic Fill & Finish Services
- Drug-Device Combination Products (DDCP)
- RUO Lyophilization

AMS manufactures IVD products, pharmaceutical, life science, and combination (DDCP) with quality, innovation and efficiency.

During the site tour following areas were reviewed

Site 1:  2841 Loker Avenue E

Microbiology, Sample Submission, Chemistry, Packaging and Kitting, Drug Product Filing, USP Water

Site 2: 1896 Rutherford Road

Pipetting, Dispensing and ELISA 96 Well Plate Manufacturing Instrumentations – Bench Smart, CyBio Well Vario

All the Quality Management System documents were reviewed as listed in Attachment B: List of Documents and Records Reviewed

All the manufacturing records for LS-SPIK products were reviewed as listed in Attachment C: ImCare LC SPIK IVD Assay Kit Components and Manufacturing Records.

Company overview slide deck was presented during audit. See Attachment E: AMS Overview Presentation - Imcare 28MAY25

During audit the manufacturing data was reviewed as follows:

1. Morning Session Meeting – [redacted] (QC Testing - AMS), [redacted] (Imcare), and Audit Team
2. Afternoon Session Meeting - [redacted] (Director of MSAT – AMS), [redacted] (Imcare), and Audit Team

[redacted]

| ISO 9001:2015 | ISO 13485: 2016 | US FDA 21 CFR 820 (or parts as indicated) | ELEMENTS | FINDINGS | | |
|---|---|---|---|---|---|---|
| | | | | Critical | Major | Minor |
| 4.1 - 4.4 | 4.1 | 5 | Quality Management System (General) | 0 | 0 | 0 |
| 7.5 | 4.2 & 7.3.10 | 20, 40, 180, 181, 184, 186 | Documentation Requirements | 0 | 0 | 0 |
| 5.1.1 & 7.1.6 | 5.1 | 20 | Leadership | 0 | 0 | 0 |
| 5.1.2 | 5.2 | N/A | Customer Focus | 0 | 0 | 0 |
| 5.2 | 5.3 | 20a | Quality Policy | 0 | 0 | 0 |
| 6.1 - 6.3 | 5.4 | 20d | Quality Objectives and Planning | 0 | 0 | 0 |
| 5.3 & 7.4 | 5.5 | 20b(1), 20b(3) | Responsibilities, Authority and Communication | 0 | 0 | 0 |
| 9.3 | 5.6 | 20c | Management Review | 0 | 0 | 0 |
| 7.1.1 | 6.1 | 20b(2) | Provision of Resources | 0 | 0 | 0 |
| 7.1.2, 7.2, 7.3 | 6.2 | 25a, 25b | Human Resources | 0 | 0 | 0 |
| 7.1.3 | 6.3 | 70f, 70g | Infrastructure | 0 | 0 | 0 |
| 7.1.4 | 6.4 | 70c, 70d | Work environment | 0 | 0 | 0 |
| 8.1 | 7.1 | 70 | Planning of Product Realization | | | |
| 8.2 | 7.2 | 30 | Customer-related Processes | 0 | 0 | 0 |
| 8.3 | 7.3 | 30a-j | Design and Development | 0 | 0 | 0 |
| 8.4 | 7.4 | 50, 80b | Purchasing | 0 | 0 | 0 |
| 8.5 | 7.5 | 20, 60, 65, 70, 75, 80, 86, 120, 130, 140, 150, 160, 170, 184, 200, 250, 21CFR801, 21CFR809 | Product and Service Provision | 0 | 0 | 3 |
| 7.1.5 | 7.6 | 72 | Monitoring and Measurement Resources | 0 | 0 | 0 |
| 9.1.1 | 8.1 & 8.2.5 | 80, 70 | Monitoring, Analysis, and Improvement | 0 | 0 | 0 |
| 9.1.2 | 8.2.1 - 8.2.3 | 198, 21CFR803, 21CFR806 | Customer Feedback | 0 | 0 | 0 |
| 9.2 | 8.2.4 | 22 | Prior Audit Findings | | | |
| 8.6 | 8.2.6 | 80, 30 | Product Release | 0 | 0 | 0 |
| 8.7 | 8.3 | 90 | Nonconforming Product | 0 | 0 | 0 |
| 9.1.3 | 8.4 | 25, 250 | Analysis of Data | 0 | 0 | 0 |
| 10.1 - 10.3 | 8.5 | 20c, 100 | Improvement | 0 | 0 | 0 |
| N/A | N/A | 21CFR11 | Electronic Signatures and Records | 0 | 0 | 0 |
| | | | **TOTAL** | 0 | 0 | 3 |

## 3.0 Finding Summary

The table above summarizes findings mapped to the applicable standards and regulations given in the current revision of the AMS Quality Manual. The rows highlighted in green are the audited sections of the applicable standards subject to this first internal audit report. Blank fields are intentional and do not have to be filled

**Total number of findings: Minor 3**
**Recommendation / Opportunity For Improvement (OFI) - 7**

## 4.0 Prior Audits

No previous audits have been checked.

## 5.0 Findings

The following tables provide details of findings from the audit

### A. Critical Nonconformities

No critical non conformities are observed.

### B. Major Nonconformities

No major non conformities are observed.

### C. Minor Nonconformities

| Finding | Citations | Nonconformity Details/ Owner/ Estimated Due Date | Evidence Reviewed |
|---|---|---|---|
| **C1** | ISO 13485:2016 Section 7.5.6 Validation of processes for production and service provision<br><br>US FDA 21 CFR §820.75 – Process Validation | [redacted] | |

## 6.0 Conclusions

The nonconformities and observations in this report are based on an evaluation of a sample of activities and procedures and reflect the professional opinion of the auditor. It is not possible for the auditors to review all documents, records, and processes, or to interview all personnel.

Findings are indicative that more or similar issues may exist. Therefore, it is the responsibility of the auditee to identify, investigate and remedy any other issues, not just those found during an audit.

This opinion is not a legal judgment as to compliance or non-compliance.

All nonconformities and recommendations noted during the audit were discussed with the supplier during the audit debrief meeting.

## 9.0 Audit Finding Definitions and Actions

| | |
|---|---|
| **Critical Nonconformity** | A “Critical” classification implies one or more of the following conditions exist:<br>• Where evidence exists that significant and unjustified departures from applicable legislative requirements has occurred with evidence that the safety of patients and/or users either has been or has significant potential to be jeopardized,<br>• Any deficiency which may make the product unfit for use or likely to present a risk for patient or user health,<br>• Inspection findings classified as critical by Regulatory Authorities and/or findings which could result in regulatory action,<br>• Notified Body and customer audit findings that are rated critical<br>• Failure to complete an inspection-related regulatory commitment in the timeframe communicated to the regulator,<br>• Data and/or reports submitted to regulators are unreliable or incomplete<br>• There are a number of major nonconformities across areas of responsibility, a pattern in multiple systems, or cumulative in the same system indicating a systemic quality assurance failure that could lead towards regulatory action by the Regulatory Authority and/or<br>• A prior major nonconformity that has recurred or has not been effectively addressed |
| **Major Nonconformity** | A "Major" classification implies that either:<br>• A required quality system element is either not present or essentially ineffective.<br>• There is a lack of adherence to a governmental regulation<br>• The current situation, should it continue, could significantly affect the safety and/or efficacy of the product or service being provided, or result in a nonconforming product or service being provided<br>• The frequency of similar minor nonconformities is such that a system failure or ineffectiveness is indicated<br>• A prior minor nonconformity that has recurred or has not been effectively addressed |
| **Minor Nonconformity** | “Minor” nonconformities are generally non-systemic and isolated in nature. A Minor Nonconformity implies that:<br>• The situation described has actual or potential impacts less significant in nature than Major Nonconformities<br>• It is an isolated issue that does not affect the safety and/or efficacy of the product or service being provided<br>• The issue could be cited as a nonconformity by a regulatory body or other 3rd party auditor |
| **Recommendation / OFI** | Recommendations, including comments or opportunities for improvement (OFIs), are <u>not</u> a category of nonconformity; however, they are suggestions regarding aspects of the quality management system that could be improved.<br>Recommendations could also include areas where there are no specific performance requirements. These are typically based on:<br>• Best practices from sites<br>• A pending governmental regulation or internal requirement<br>• A recommended standard or guideline published by a regulatory agency or trade association, such as FDA or ISO |

**Audit Finding Response Requirements**

**"Critical Nonconformity"** findings must be submitted to the CAPA system no later than five (5) business days from the notification of the Critical Nonconformity.

**"Major Nonconformity"** findings must be submitted to the CAPA system no later than ten (10) business days from the notification of the Major Nonconformity.

**"Minor Nonconformity"** findings must be submitted to the CAPA system within 30 business days from the issuance of the audit report.

All **Critical, Major and Minor Nonconformities** each require an initial documented corrective action plan (CAP) to be submitted to the auditors within thirty (30) business days. The CAPs need to include the following items:

- CAPA reference number
- Investigation summary
- Approximate root cause(s)
- Plan for correction(s) and corrective action(s), as well as preventive action(s) (if applicable)
- Planned completion date(s) of action(s)
- Plan for checking effectiveness of action(s)

**Recommendations** or **opportunities for improvement**, do not require formal documented CAPs; however, it is highly recommended that they be given consideration for continuous improvement.

The Auditee is responsible for requesting any changes or amendments to this audit report within fifteen (15) business days of report issuance.

## 10.0 Attachments

Attachment A: Audit Agenda and Attendees

Attachment B: List of Documents and Records Reviewed

Attachment C: ImCare LC SPIK IVD Assay Kit Components and Manufacturing Records.

Attachment D: Good Manufacturing Practices for LC-SPIK MCA Coated ELISA 96 Well Plate

Attachment E: AMS Overview Presentation - Imcare 28MAY25