

A background image showing a medical professional's hands holding a tablet. The tablet screen displays a brain analysis interface with a 3D brain model, red glowing nodes, and a network of lines. A stethoscope hangs from the professional's neck. The overall theme is medical technology and research.

Committed to
Improving Lives

GLOBAL SUPPLIER QUALITY EXPECTATIONS MANUAL

INTEGRA LIFESCIENCES

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Dear Supplier,

The Integra LifeSciences Codman Specialty Surgical and Tissue Technologies Divisions are committed to sustaining our reputation as a quality organization by upholding the standards and requirements of regulatory compliance of all business units by:

- Assuring the safety, quality, and integrity of products,
- Assuring data accuracy, records integrity, and preservation of products,
- Partnering with suppliers, customers, and employees to continually improve quality and meet regulatory requirements.

This Supplier Quality Expectations Manual (SQM) establishes Integra's quality expectations for our Suppliers and will be used to assist in our supplier selection process. The expectations are in alignment with ISO 13485, FDA 21 CFR Part 820, and ISO 9001 and are essential for the effective management of the products we provide to our customers.

The content of this SQM supplements drawings and specifications, purchase orders, and agreements between Integra and our Suppliers. If the provisions of this SQM are inconsistent with legally binding requirements, drawings/specifications, purchase orders, agreement, or statement of work the foregoing documents shall prevail over this SQM.

We recognize that Integra has a wide variety of supplier types that provide an array of products and services. Hence, the requirements and expectations stated in this SQM may apply differently, depending on the goods or services supplied to Integra. Please review the SQM content and notify your Integra representative if there are any concerns about your organization's ability to align with our expectations.

We look forward to partnering with you!

Jessica W Smith

28/10/2024

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Corporate Vice President, Global Quality and Chief Regulatory Officer

Richard Eisner

21/10/2024

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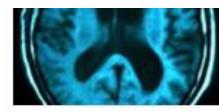
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Kanwar Singh

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Director, Global Supplier Quality





Quality Policy

The companies of Integra LifeSciences stand for integrity – of our people, our products and our partners.

- We are committed to providing life saving products that are safe and effective.
- We are committed to continuously improve the effectiveness of our Quality Management System, our products and our services.
- We are committed to meeting the regulatory requirements and to satisfying the needs of our customers and partners.
- We strive to deliver high quality products and services to achieve total customer satisfaction.

The products manufactured by the companies of Integra LifeSciences provide state of the art medical technology that improves the quality of life for the patients we serve.

WWCP-001 Rev 018



1.0 Purpose and Scope

The purpose of this Supplier Quality Manual is to communicate Integra LifeSciences's (Integra) expectations to Suppliers during the supplier selection process. These expectations apply to the development, manufacture, and delivery of goods and/or services supplied to Integra.



2.0 General Supplier Expectations



Suppliers are responsible for ensuring that goods and/or services they provide to Integra meet Integra's documented requirements. Audits, approvals or verification by Integra of the Supplier's quality system, infrastructure, controls, acceptance activities, etc., do not absolve the Supplier of accountability and responsibility to provide goods and/or services conforming to Integra documented requirements.

2.1 QUALITY AGREEMENTS

In addition to the expectations contained in this Supplier Quality Manual, a Supplier Quality Agreement may be required and executed to outline specific requirements and responsibilities applicable to the goods and/or service provided by the Supplier.

2.2 NON-DISCLOSURE AGREEMENTS

Information provided to Suppliers by Integra may include confidential information, including proprietary information of Integra or its partners. As a result, Suppliers may be asked to sign the Integra Non-Disclosure Agreement (NDA) before such information is disclosed.

It is Integra's policy that,

- Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the NDA or other written agreement governing the disclosure of confidential information.
- Suppliers shall not make or authorize any public announcement, issue any press release concerning the existence of any relationship with Integra, or disclose the terms of any agreement with Integra without Integra's prior written consent.
- Suppliers shall not display, use, or reproduce Integra's logo, trademarks, trade dress, or copyrighted materials in any manner without Integra's prior written consent.

2.3 ENVIRONMENTAL COMPLIANCE

Goods and services supplied to Integra are expected to meet the requirements of the latest version of all applicable country, federal, state and local environmental regulations. The link below references and includes, but is not limited to, such regulations. Integra may require that Suppliers submit proof of certification of compliance with the applicable regulations.



Integra's Environmental, Health and Safety (EHS) policy is included in the following link: [EHS Poster No Signatures 9-22-2022.indd \(integralife.com\)](#).

The chemical composition of a product supplied by Supplier may result in the need for Supplier to demonstrate additional compliance obligations not appearing in the list below. If Supplier becomes aware or reasonably believes that products supplied to Integra are not compliant, Supplier must immediately notify Integra.

- California Proposition 65 -Safe Drinking Water and Toxic Enforcement Act of 1986
- China RoHS 2, Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products - Order 32
- EU Waste Framework Directive and amendment on SCIP database
- Animal Derived Material (ADM) – FDA Guidance
- EU Packaging Directive and amendments
- EU MDR - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- EU Persistent Organic Pollutants (POPs)
- EU REACH Regulation
- EU RoHS 2 Directive and amendment (EU)
- EU WEEE Directive
- FDA 21 CFR 801.437 - Natural Rubber Latex

The latest Standard applicable to the product and/or manufacturers region shall be considered.



2.4 BUSINESS CONTINUITY

Integra expects Suppliers to implement and maintain a documented Business Continuity Plan (“BCP”) to ensure the uninterrupted supply of products and services to Integra. We expect Suppliers to have comprehensive plans, processes, and procedures in place to enable rapid, effective response and recovery of business operations and the supply of products and services in the event of disruptions or unplanned incidents. The BCP should address, at a minimum: identification of essential operations, processes, and procedures necessary to maintain the continuous supply of products and services to Integra; evaluation and identification of potential risks and threats that could impact the supply chain, including equipment, materials, and components sourced from third parties; detailed procedures for responding to and managing the identified risks and threats; and a robust communication strategy that includes timely escalation procedures and identification of a designated management team and contact person responsible for coordinating with Integra in the event of a disruption. Suppliers must ensure that their BCPs are regularly reviewed, updated and tested to remain effective and aligned with Integra’s requirements.

3.0 Quality Management System

Suppliers that supply finished medical devices and select Suppliers are expected to implement and maintain, at a minimum, an established Quality Management System (QMS) that is aligned with ISO 13485, FDA 21 CFR Part 820, ISO 9001 or other comparable, recognized standard or regulation.

Suppliers that provide finished medical devices are also expected to complete FDA establishment registration and device listing requirements per FDA 21 CFR Part 807.

Additionally, the following shall be considered minimum QMS expectations for all Suppliers partnering with Integra:

3.1 GENERAL

- It is expected that the effectiveness of the QMS be maintained in accordance with the applicable regulations and standards.
- Suppliers shall notify Integra of any QMS change that may impact products, components, or otherwise, either directly or indirectly, that are sold to Integra and shall not implement any change without Integra written consent.
- Change to the QMS shall be controlled to ensure compliance with applicable regulatory requirements and standards.
- Records shall be maintained to demonstrate conformance to applicable regulatory requirements and standards and shall be made available to Integra upon request.

3.2 MANAGEMENT RESPONSIBILITY

Management Commitment

The Supplier's senior management is expected to demonstrate a commitment to continuous improvement. It is expected that senior management provide documented evidence of its commitment to the development and improvement of the Quality Management System by:

- Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements.
- Establishing the quality policy and objectives.
- Conducting quarterly or more frequent, as appropriate, quality system reviews on the effectiveness of the quality system and taking appropriate and timely action when indicators are unfavorable.
- Ensuring the availability of necessary resources.



Resource Management

- Suppliers are expected to provide the resources necessary to implement and maintain an effective Quality Management System and to continually improve its effectiveness.
- Employees of the Supplier are expected to be qualified for the job they perform through education, training, and/or work experience, and be knowledgeable of appropriate quality tools, defect awareness, and processes that affect the quality of products and services provided to Integra.
- Suppliers are expected to maintain evidence of required and completed training.
- Suppliers are expected to maintain an appropriate work environment to prevent adverse effects on product quality.

Customer Focus

The Supplier's senior management is expected to ensure that customer needs and expectations are identified, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. Integra expects that Suppliers conform to design and performance specifications. Suppliers are expected to meet requirements for reliability, delivery, cost management, and technical support.



3.3 DOCUMENTATION

The Quality Management System documentation is expected to include, at a minimum:

- ✓ Documented statements of a quality policy and quality objectives.
- ✓ Documented procedures as required by the Quality Management System.
- ✓ Documents needed by the organization to ensure the effective planning, operation, and control of its processes.
- ✓ Records required by the Quality Management System.

Control of Documents

- Suppliers are expected to establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System.
- Suppliers are expected to have a documented procedure for the control and distribution of drawings, documents and/or standards.
- Obsolete documents are expected to be destroyed or appropriately identified as such for limited distribution.

Control of Records

- Records are expected to be stored in an environment that will prevent deterioration, damage, or loss, and are expected to be readily accessible to Integra upon request.
- Suppliers will make available any and all quality records, in a timely manner, upon request by Integra or any regulatory body such as the FDA.
- Electronic record approvals and storage are expected to comply with 21 CFR Part 11 requirements.
- All quality records are expected to be retained for a period of time equivalent to the design and expected life of the device.

3.4 PURCHASING AND SUB-TIER SUPPLIER CONTROL

- Suppliers are expected to establish and maintain controls on the purchase of goods and/or services used in the manufacture of products for Integra to ensure conformance to specified requirements.
- Purchasing Controls include:
 - ✓ Evaluation, selection, and qualification of Suppliers to pre-determined criteria.
 - ✓ Verification of purchased products via inspection and/or test, where applicable.
 - ✓ Monitoring of Supplier performance, change control, and documentation requirements.
- If, with Integra's knowledge and approval, the Supplier subcontracts a portion of the manufacture and/or inspection of products to sub-tier Suppliers, the expectations described in this manual are expected to be passed on to those Suppliers. Suppliers are expected to remain responsible for all acts or omissions of their sub-tier Suppliers.
- Suppliers shall notify Integra prior to implementing sub-tier Supplier changes. Integra approval may be required depending on the scope of change and potential impact to Integra product.
- Integra may choose to evaluate the Supplier's sources to ensure the purchased product or service meets specified purchase agreements.

3.5 CHANGE MANAGEMENT

- It is expected that Suppliers have an established process to review, approve, and maintain initial released documents and changes to released documents.
- Integra Purchasing shall be notified in advance of all changes planned by the supplier or sub-tier suppliers that involve the product supplied to Integra.
- Notification of changes shall be formally acknowledged by Integra Purchasing.



3.6 PRODUCT AND PROCESS ENVIRONMENT

- It is expected that buildings & facilities used in the manufacture of the product supplied to Integra be designed, constructed, and maintained to facilitate cleaning, maintenance & operations & to ensure orderly placement of equipment & materials to prevent mix-up and contamination to the type and stage of manufacturing.
- Suppliers are expected to manufacture, test, package, and store the product and materials in an environment meeting the applicable GMP regulations, which is designed, constructed and maintained in a manner that,
 - a) permits the operation therein to be performed under clean, sanitary, and orderly conditions,
 - b) prevents the contamination of the product and the addition of extraneous material to the Product.
- It is expected that Suppliers establish & maintain a program for environmental monitoring, tracking, & trending processes.
- Suppliers are expected to maintain and document an adequate pest control program.

3.7 PRODUCTION AND PROCESS CONTROLS

- It is expected that line clearance be performed at the start and finish of each lot and documented within the QMS (e.g. Device History Record).
- Validation/qualification of all critical systems, utilities, equipment, instruments, release test methods, software, and processes used for the manufacture and control of product is expected to be performed and documented.
- Suppliers are expected to establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to ensure products and processes conform to applicable requirements. Suppliers are expected to calibrate these devices at consistent periodic intervals against applicable standards traceable to recognized national and/or international standards. Integra shall be immediately notified if a Supplier finds that a gauge is not calibrated correctly or a gauge with expired calibration was used to verify parts that were delivered to Integra, and it was confirmed that product quality may have been impacted.
- Measurement System Analysis is expected for any system used to measure/test CTQ's.
- First Article Inspection is expected for all components manufactured by the Supplier.
- Suppliers are expected to develop and maintain Control Plans, at minimum, for all processes that require process validation.
- Suppliers are expected to maintain manufacturing records that contain, at minimum, the product number, lot number, quantity, and date of manufacturing for all products manufactured for Integra. Integra shall be permitted to inspect these records.
- It is expected that traceability be recorded and maintained for all materials used for products manufactured for Integra. Records shall contain, at a minimum, the item number, lot number, date of manufacturing, and quantity for all products used in and shipped to Integra. Integra shall be permitted to inspect these records upon request.
- It is expected that procedure to protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution be maintained by the Supplier.

3.8 LABELING

- Suppliers are expected to establish and maintain a process for label reconciliation for labels applied to finished devices.
- It is expected that labels and packaging be verified prior to use and throughout all production steps.
- Packaging and labels for finished devices shall be approved by Integra prior to release of the final product.

3.9 MONITORING AND MEASUREMENT

Incoming Acceptance

- Suppliers are expected to have procedures for evaluation of incoming products, including inspection, testing, and verification as conforming to Integra specifications.
- Suppliers are expected to document acceptance or rejection of all incoming products supplied to Integra.
- Statistically relevant, risk-based sampling plans are expected to be applied.

In-Process Acceptance

- Suppliers are expected to have in-process acceptance procedures to ensure that in-process products are controlled until the required inspection and tests, or other verification activities have been completed, or necessary approvals are received.
- Statistically relevant, risk-based sampling plans are expected to be applied.

Final Acceptance

- Suppliers are expected to have procedures for final product acceptance and release to ensure that each production unit, lot, or batch of finished product meets Integra's acceptance criteria.
- Final product inspection/test using statistically relevant, risk-based sampling plans are expected to be performed for each lot manufactured and shipped.
- It is expected that finished product be adequately controlled until released.
- Shipping records shall be developed and maintained, and product traceability shall be recorded for each lot manufactured and shipped.
- The supplier is expected to provide a Certificate of Conformance/Analysis with each shipment that includes date of manufacture, lot number, drawing/revision number and quantity, as applicable.

3.10 NONCONFORMING PRODUCT

- Suppliers shall immediately notify Integra of nonconformances identified that are related to products shipped to Integra.
- A Supplier Corrective Action Requests (SCAR) will be initiated for all nonconformances related to product supplied by the Supplier. Prompt Supplier response is expected.
- Suppliers shall contain potentially affected products, perform root cause analysis, and implement appropriate corrective and preventive actions in a timely manner. Related records shall be made available to Integra upon request.
- Upon request, Suppliers will be expected to assist Integra with failure investigations that involve products provided by the Supplier. Related records shall be made available to Integra upon request.

3.11 AUDITS

Supplier - Internal

- Suppliers are expected to routinely audit their QMS for effectiveness.
- Suppliers are expected to establish a system to record traceability between corrective and preventive actions and internal audits findings.

Supplier - External

- It is expected that Integra be immediately notified of any regulatory action taken against the Supplier that would affect goods availability or bring into question the quality and safety of the goods sourced by Integra.
- Upon request, the supplier shall provide Integra reports from external inspection and audits.

Integra

- Integra utilizes a comprehensive process to qualify and manage Suppliers. Supplier Audits are an integral part of this process. The Supplier shall allow Integra to visit the facility(s) to review any activities pertaining to products provided to Integra.
- The Supplier shall allow Integra's Notified Body to conduct unannounced audits.

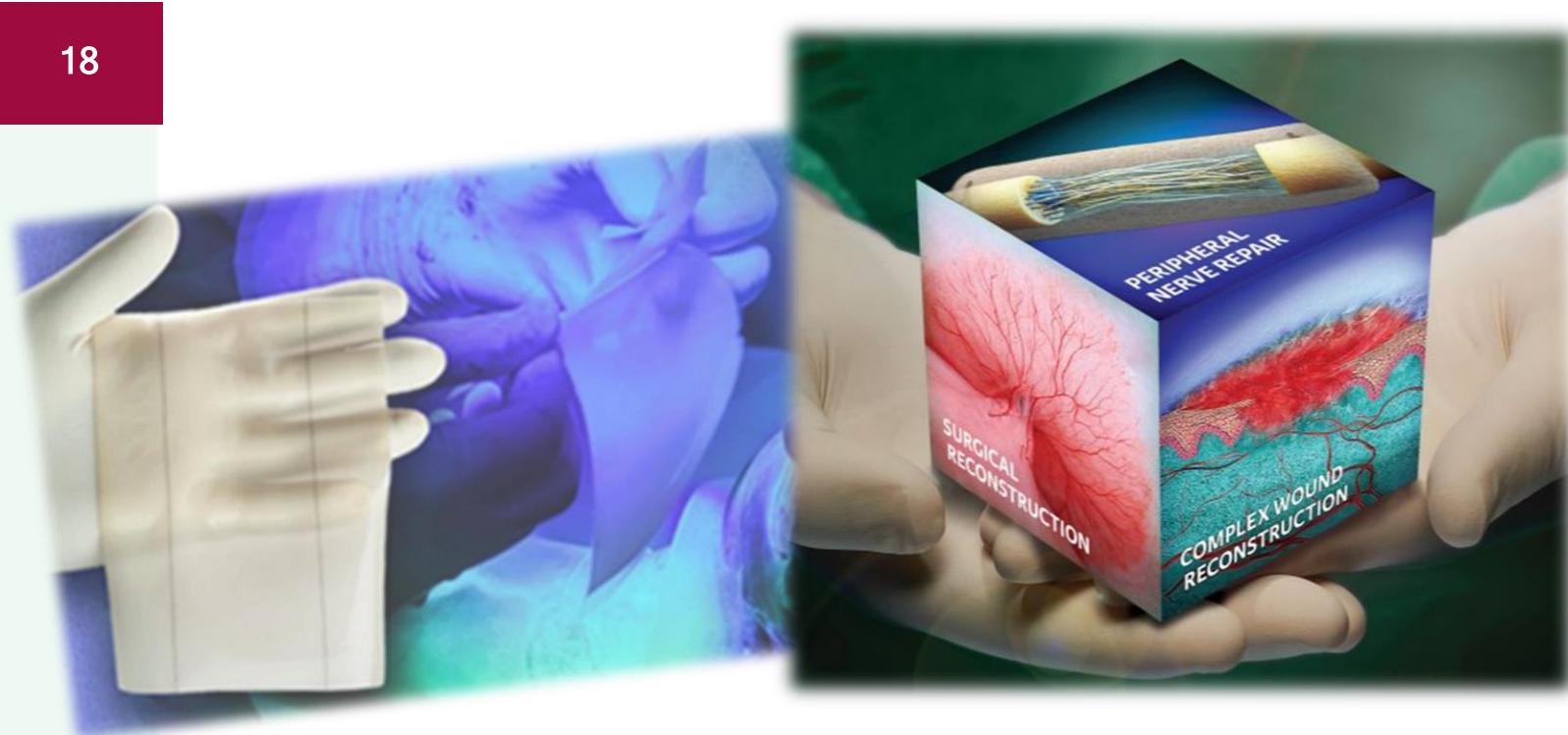
3.12 COMPLAINTS AND ADVERSE EVENTS REPORTING

- Integra has the responsibility to correspond with all applicable regulatory authorities with respect to complaints and adverse events related to the product labeled and distributed by Integra. Related Supplier requirements will be defined in the Supplier Quality Agreement, but in general Suppliers are expected to cooperate in dealing with customer and third-party complaints and adverse events concerning the product supplied to Integra and are expected to take action to promptly resolve such complaints and adverse events.
- As it pertains to products supplied to Integra, Suppliers are expected to:
 - ✓ Give prompt notice to Integra by email or by telephone as soon as becoming aware of a Product complaint or adverse event and provide written follow-up to Integra.
 - ✓ Maintain a written record of all customer and third-party complaints and adverse events that relate to the product supplied to Integra, whether received orally or in writing.
 - ✓ Establish a tracking and traceability system for all products to permit successful tracking in the event of a recall.
 - ✓ Maintain complaint and adverse event records and files in accordance with quality system requirements.



3.13 FIELD ACTIONS

- If either party determines that a field corrective action or other action (e.g. Product Hold Order) involving a product shipped to Integra should be considered, it will immediately notify the other party.
- Integra will have the sole authority to determine whether any action such as a field corrective action or other action shall be undertaken where it owns the design and regulatory approval.
- Suppliers are expected to cooperate with Integra to implement the action once the determination is made.



4.0 Tissue Technologies

The following expectations only apply to Suppliers partnering with Integra Tissue Technologies division.

4.1 ABATTOIR EXPECTATIONS

- The Supplier will ensure traceability of all materials back to the source plant herd.
- The Supplier will source materials from approved countries and certify the originating country in writing. The sourced country / zone must have negligible or controlled risk for TSE / BSE.
- The Supplier will provide evidence in every shipment that source material is slaughtered and collected at government-monitored facilities.
- The Supplier will source material that is considered fit for human consumption excluding fetal bovine and porcine.
- The Supplier will provide written evidence of the following:
 - ✓ Government regulations document(s)
 - ✓ Certificate of Compliance / Conformance documentation
 - ✓ Veterinary Permits
 - ✓ Segregation of animals in facility
 - ✓ No cross-contamination
 - ✓ Cleaning and sanitation processes
 - ✓ Method of animal stunning

4.2 HUMAN TISSUE REQUIREMENTS

- Tissue banks are defined as an entity that provides or engages in one or more services involving tissue from living or deceased persons for transplantation purposes. These services include obtaining authorization and/or informed consent, assessing donor eligibility, testing, recovery, collection, acquisition, processing, storage, labeling, distribution and dispensing of tissue.
- Any tissue imported from entities outside U.S. jurisdiction that do not follow AATB Standards shall be appropriately quarantined throughout import, storage, processing, and export. The AATB-accredited tissue bank must verify that the foreign tissue bank not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., informed consent/authorization, donor eligibility assessment, recovery, acquisition, donor testing). Additionally, the tissue bank not accredited by the AATB should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's "Safety of Human Cells, Tissues and Organs for Transplantation Regulations;" the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or expectations as described in the World Health Organization's Aide- Memoire for Human Cells and Tissues for Transplantation.
- Importer of record must notify, either before or at the time of importation, the director of the district of the Food and Drug Administration (FDA) having jurisdiction over the port of entry through which the HCT/P is imported or offered for import and must provide sufficient information, including information submitted in the Automated Commercial Environment (ACE) system or any other electronic data interchange system authorized by the U.S. Customs and Border Protection Agency as required, for FDA to make an admissibility decision. Until an admissibility decision is made by FDA, the HCT/P may be transported under quarantine to the consignee, while the FDA district reviews the documentation accompanying the HCT/P. When the FDA makes a decision regarding the admissibility of the HCT/P, FDA will notify the importer of record.
- The following tissue bank regulation should be considered:
 - U.S. Food & Drug Administration (FDA) - 21 CFR 1271 (either 351 or 361 of PHS).
 - American Association of Tissue Banks (AATB)
 - State Governments – individual states may require that a tissue bank be accredited by AATB.
 - Labs must be certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493 or have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

- Tissue banks outside the United States/United States Territories not accredited by the AATB must comply with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., informed consent/authorization, donor eligibility assessment, recovery, acquisition, donor testing). Additionally, the tissue bank not accredited by the AATB should be verified to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's "Safety of Human Cells, Tissues and Organs for Transplantation Regulations;" the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or expectations as described in the World Health Organization's Aide-Memoires for Human Cells and Tissues for Transplantation. Depending on the tissue type, antibody test result and how this impacts the suitability of the donor's tissues for transplantation may differ from country to country, due diligence for acceptability or equivalence should be made here.
- For Integra, any Tissue Bank used as a supplier must be registered with the FDA for each Tissue Bank function they provide and list every HCT/P that the establishment manufactures within 5 days of beginning operations.
- Tissue banks must screen a donor of cells or tissue by reviewing the donor's relevant medical records. Donors must, at minimum, be free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases; and be free from communicable disease risks associated with transplantation.
- Establishments that recover HCT/Ps must recover in a way that does not cause contamination or cross-contamination during recovery, or otherwise increase the risk of the introduction, transmission, or spread of communicable disease through the use of the HCT/P.
- Recovery must be done in a hospital or birthing suite.
- Tissue establishments must establish and maintain procedures to control the labeling of HCT/Ps.
- Tissue establishments must ensure that equipment used/processes must be validated.
- Tissue establishments must store tissue at appropriate temperatures as established with the intent to inhibit the growth of infectious agents.
- Tissue establishments must maintain and record storage temperatures for HCT/Ps and periodically review recorded temperatures to ensure that temperatures have been within acceptable limits.

5.0 Regulatory Compliance

The below standards and regulations may apply, where applicable, to Suppliers providing products and services to Integra. The below list is not comprehensive and other standards and regulations may also apply:

- Annex II AIMDD - Active Implantable Devices
- Annex II MDD - Medical Devices
- ARGMD - Australian regulatory guidelines for medical devices
- Brazil RDC – GMP Requirements for Medical Devices and IVDs
- CMDR, SOR/98-282 – Canada Medical Devices Regulations
- Batteries and Waste Batteries, Regulation
- EU MDR - Regulation (EU) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- EU RoHS 3 Amendment
- FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures
- FDA 21 CFR Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies (cGLP)
- FDA 21 CFR Part 210 - Current Good Manufacturing Practice in Manufacturing Processing, Packaging, or Holding of Drugs
- FDA 21 CFR Part 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals
- FDA 21 CFR 801.437 - Natural Rubber Latex
- FDA 21 CFR Part 801 - Labeling
- FDA 21 CFR Part 803 - Medical Device Reporting
- FDA 21 CFR Part 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- FDA 21 CFR Part 820 - Quality System Regulation
- Food and Drug Regulations, C.R.C., c. 870, Part C, Division 2, Good Manufacturing Practices (GMPs)
- ISO 13485 / EN ISO 13485 – Medical Devices – Quality management systems – Requirements for regulatory purposes
- ISO 14001 Environmental Management Systems
- ISO14971 / EN ISO14971 – Medical devices – Application of risk management to medical devices
- Korea Ministry of Food and Drug Safety (MFDS) Medical Device Act
- Mexico, Ley General de Salud
- MHLW GMP Ordinance #169 – Japan Quality Management System Compliance
- SMDO – Switzerland Medical Devices Ordinance – Switzerland (812.213)
- The Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations
- UK Medical Devices Regulation – UK MDR as amended by the EU exit regulations

The latest Standard applicable to the product and/or manufacturers region shall be considered.



6.0 Code of Conduct for Business Partners

Integra's Code of Conduct for Business Partners (the "Code of Conduct") applies to all individuals and organizations that are Suppliers to or Third- Party Intermediaries¹ for Integra ("Business Partners"). This Code of Conduct sets minimum requirements and expectations for the conduct of Integra's Business Partners; however, Integra encourages our partners to establish stricter or more extensive requirements where appropriate.

Link to

[Integra Code of Conduct for Business Partners](#)

¹ Third-Party Intermediaries' include distributors, sub-distributors, sales agents, and other third-parties registering, promoting, selling, or supplying Integra products or otherwise interacting with government officials (includes any State or National government department, ministry, agency, instrumentality, military organization, government-owned or controlled company, political party or a former/current elected official, public international organization, or any employee or official of the above.) or healthcare providers on Integra's behalf.



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