Quality Management System

MANUAL

SDIX, LLC
Headquarters: 111 Pencader Drive
Newark, Delaware 19702

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CORPORATE OVERVIEW

SDIX, LLC is a biotechnology company with a core expertise in development and production of antibodies and assays for the pharmaceutical, biotechnology and in-vitro diagnostic markets. With over 20 years experience, SDIX has developed a unique set of technologies and capabilities from immunogen design to creation of high quality assays enabling our client to meet research, diagnostic and commercialization objectives. The company offers a range of products and services, including custom antibodies, in-vitro diagnostic grade antibodies, proprietary critical reagent products, associated bioprocessing services and custom assay design and development services. By applying its core competencies of antibody and assay development, the company serves the pharmaceutical, biotechnology and diagnostic markets both in the United States and Internationally.

The company is a wholly-owned subsidiary of OriGene Technologies. SDIX sites utilize the same Quality Management System (QMS) with both global and site-specific SOPs as necessary. The SDIX QMS is independent of the quality systems of OriGene Technologies.

The Company operates facilities in the United States:

- Corporate Headquarters: Pencader Dr., Newark, Delaware
  - Corporate Headquarters
  - Administration
  - Sales and Marketing
  - Purchasing and Materials Control
  - Technical Development
  - Quality Assurance and Quality Control
  - Custom Critical Reagents
  - Cell Culture
  - Monoclonal Antibody Production

- Polyclonal & Monoclonal Manufacturing & Services: Windham, Maine
  - Polyclonal Antibody Production
  - Cell Culture
  - Upstream Monoclonal Production
  - Technical Development
  - Quality Assurance

1.0 SCOPE

This document outlines the Quality Management System components for SDIX and offers an interpretation between the system and our key normative references: ISO 13485:2016 (Medical Devices - Quality Management Systems-Requirements for regulatory purposes) and 21 CFR Part 820, as applicable. SDIX maintains one Quality Management System for all facilities, which applies to all aspects of product life cycle from methods, controls, design, manufacture, packaging, labeling, storage, shipment, post-release quality surveillance for products and services provided by SDIX. This enables the company to address and achieve customer satisfaction through the effective application of the system, including processes for continual improvement and the prevention of nonconformity.

1.1 Exclusions:

The products and services provided by SDIX which are “For further manufacturing” (i.e. OEM, Contract Manufacturing, Fee for Service) and “for Research Use Only” are excluded from Design and Development (7.3).

1.2 Not Applicable:

SDIX does not provide the following services/product therefore these are considered not applicable

Installation Activities (7.5.3)

Servicing Activities (7.5.4)

Particular requirements for sterile medical devices (7.5.5 & 7.5.7)

Particular requirements for active implantable medical devices and implantable medical devices (7.5.3.2.2 & 8.2.4.2)

2.0 REFERENCE DOCUMENTS

2.1 ISO 13485:2016 Medical Devices - Quality Management Systems- Requirements for regulatory purposes

2.2 FDA Code of Federal Regulations, 21 CFR Part 820, Quality Systems Regulation, as applicable
2.3 REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
2.4 ISO 14971:2012 Medical devices – Application of risk management to medical devices
2.5 ISO 9001:2015 Quality Management Systems -- Requirements
2.6 SDIX Quality System SOPs
2.7 FDA Code of Federal Regulations, 21 CFR Part 809, In Vitro Diagnostic Products for Human Use, as applicable
2.8 FDA Code of Federal Regulations, 21 CFR Part 801, Labeling, as applicable
2.9 FDA Code of Federal Regulations, 21 CFR Part 803, Medical Device Reporting, as applicable

Distribution
Management Representative is responsible for the controlled internal & external distribution of this manual, and changes thereto. Personnel have access to the latest revision of our Quality Manual through the company internal network (i.e. Intelex).

3.0 TERMS AND DEFINITIONS

Intelex	Intelex Technologies' web-based Quality Management Software suite.
Nonconformance	Any product that does not meet defined internal and/or external specifications.
SDIX Business Management Team (i.e. Top Management)	For purposes of this document, this refers to the VP & General Manager of SDIX, LLC and their direct reports.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements,

4.1.1 SDIX has documented a Quality Management System (QMS) in accordance with the requirements of the ISO 13485:2016 Standard and applicable regulatory requirements, such as 21 CFR Part 820, as applicable.

SDIX shall establish, implement, and maintain and requirement, procedure, activity or arrangement required to be documented by ISO 13485:2016 or applicable regulatory requirements.

The role of SDIX, LLC is a manufacturer of antibodies for the pharmaceutical, biotechnology and in-vitro diagnostic markets.

4.1.2 This is not a stand-alone system, but is integrated within SDIX's operating discipline which encompasses the policies, requirements, and work processes of Technical Development, Antibody Development, Production Planning, Quality Control, Operations, Customer Service, Shipping,

Sales & Marketing and Quality Assurance. Refer to SDIX High Level Process Flow Chart FC 4.1.1

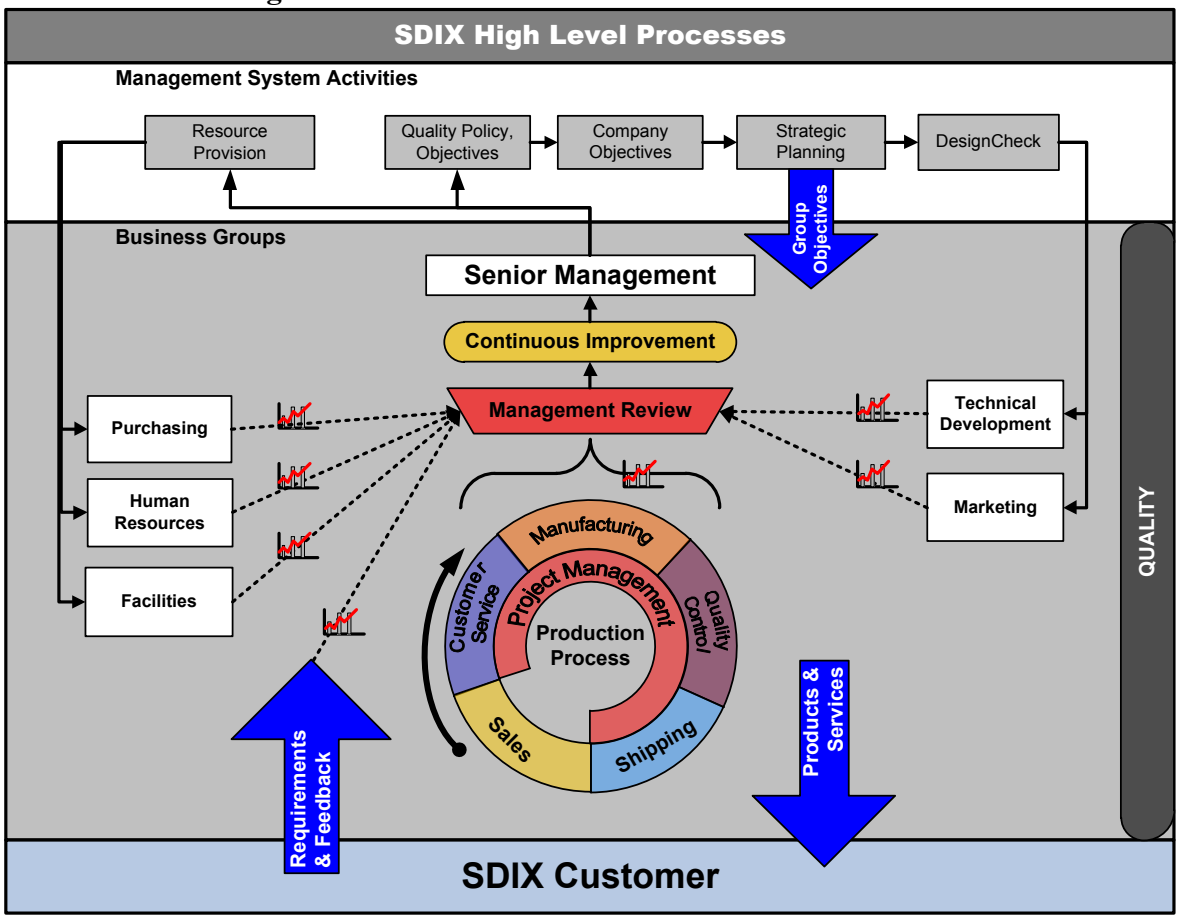
Developed and endorsed by company management the QMS ensures that customers' receive quality, reliability and integrity in the products and services. The QMS calls for precise adherence to specifications, as well as legal and quality requirements, as applicable.

Product quality is maintained through systems of standardization and process control. Service quality covers all aspects of customer transactions and is ensured by the function that is providing the service.

SDIX shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;
b) Aply a risk based approach to the control of the appropriate processes needed for the quality management system;
c) Determine the sequence and interaction of these processes.

FC 4.1.2.1 SDIX High Level Processes Flow Chart



4.1.3 For each Quality Management system process, SDIX shall:

a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective. Refer to SDIX Quality Management System SOPs.

b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes. Refer to Management Responsibilities and QMS Review SOP G5505.

c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

d) monitor, measure as appropriate, and analyze these processes. Refer to Refer to Management Responsibilities and QMS Review SOP G5505.

e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements.

4.1.4 SDIX shall manage these quality management system processes in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements. Changes to be made to these processes shall be (refer to Document Control SOP G5513):

a) evaluated for their impact on the quality management system;

b) evaluated for their impact on product produced under this quality management system;

c) controlled in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements.

4.1.5 SDIX has minimal outsourcing. In the event that outsourcing is needed, SDIX shall monitor and ensure control over such processes as per Supplier Quality System G5516. Additionally, SDIX shall retain responsibility of conformity to ISO 13485:2016 and applicable regulatory requirements for outsourced processes. Controls shall be proportionate to the risk involved and the ability of the external party to meet requirements and shall include written quality agreements.

4.1.6 SDIX shall document procedures for validation of computer software used in the Quality Management System as per Validation Master Plan SOP G5807. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or application. The specific approach and activities associated with software validation and revalidation shall be proportionate to risk associated with the use of the software.

Records of the validation/revalidation activities shall be maintained as per Validation Master Plan SOP G5807.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

a. a documented quality policy and objectives;
b. quality manual;
c. documented procedures required by ISO 13485:2016 and 21 CFR Part 820, as applicable;
d. documents, including records, determined by the SDIX to be necessary to ensure the effective planning, operation and control of its processes;
e. other documentation specified by applicable regulatory requirements.

4.2.2 Quality Manual

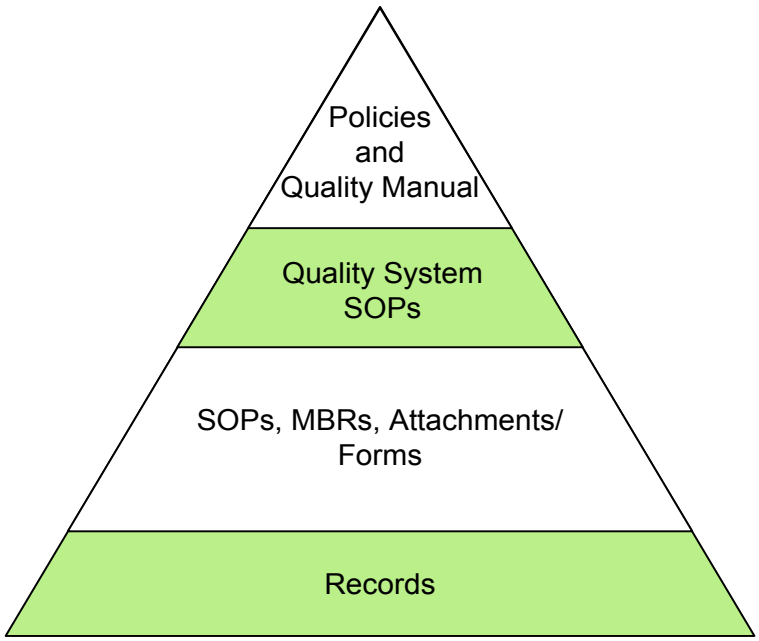
This Quality Manual has been prepared to describe SDIX's QMS. It includes:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application. The scope and permissible exclusions of the QMS are described in section one of this manual.

b) The documented procedures for the quality management system or reference to them. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section.

c) A description of the interaction between the processes of the quality management system. SDIX High Level Process Flow Chart FC 4.1.2.1 provides a description of the interaction between the processes of the QMS system.

The Quality Manual outlines the structure of the documentation used in the quality management system. The Quality Manual is the top tier of our documentation system. The Quality Manual is an overview of our quality system. The second tier of our documentation system is our quality system standard operating procedures (SOPs). The third tier of the documentation system consists of our working instructions (i.e. manufacturing SOPs, quality control SOPs, RMSRs, forms, master batch records, and specifications). The fourth tier of the documentation system consists of the quality records (i.e. objective evidence).



4.2.3 Medical Device File

For each product type or family, SDIX shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of ISO 13485:2016 and compliance to applicable regulatory requirements (i.e. Master Batch Records, SIPOCs, Product-Specific CoA templates).

The content of the file shall include, but is not limited to:

a) general description of the product, intended use/purpose, and labeling, including any instructions for use;
b) specifications for product;
c) specification or procedures for manufacturing, packaging, storage, handling, and distribution;
d) procedures for measuring and monitoring;
e) as appropriate, requirements for installation;
    a. Not Applicable
f) as appropriate, procedures for servicing;
    a. Not Applicable

4.2.4 Control of Documents

Documents required by the quality management system are controlled according to Document Control SOP G5513. Records are a special type of document and are described in section 4.2.5. Document Control SOP G5513 defines the controls needed to:

a.) to review and approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible, readily identifiable,
f) to ensure that documents of external origin determined by SDIX to be necessary for the planning and operation of the QMS are identified and their distribution controlled,
g) to prevent deterioration or loss of documents,
h) to prevent the unintended use of obsolete documents, and to apply suitable identification to them.

Changes to documents are reviewed and approved by either the original approving function or another designated function, having access to pertinent background information upon which to base its decisions.

SDIX defines the period for which at least one copy of obsolete documents are retained. This period ensures that documents to which product has been manufactured and tested are available for at least the lifetime of the product but not less than the retention period of any resulting record or as specified by applicable regulatory requirements. Obsoleted documents are retained as defined in SDIX's Record Control SOP G5526.

4.2.5 Control of Records

Quality Records are maintained to provide evidence of conformity to requirements and the effective operation of the quality management system.

SDIX documents procedures defining controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The records are maintained according to the procedure Record Control Policy G5526.

Protection of confidential health information: Patient information/health information is not provided to SDIX or recorded in SDIX records. Employee health screening information is treated as confidential records and with limited and controlled access to the records.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

SDIX retains records as per G5526.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

The SDIX Business Management Team (i.e. Top Management) takes a visible and leading role in creating and sustaining core values, policies, strategies, directions, performance expectations and customer focus. The SDIX Business Management Team leads the implementation of the quality management system that promotes excellence. Leadership from all levels of the company provides evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources

5.2 Customer Focus

SDIX views its product and service quality as being defined by its customers. SDIX works closely with its customers to understand their businesses and their expectations. This close working relationship helps SDIX better meet its customer's expectations today and to anticipate and meet their needs in the future.

The SDIX Business Management Team ensures that not only are customer requirements and applicable regulatory requirements understood, but they are determined and met with the aim of enhancing customer satisfaction.

Customer requirements are determined, converted into internal requirements and communicated to the appropriate people within the organization through Production Planning for Delaware SOP G5616, Polyclonal Scheduling SOP G2428 and Order Fulfillment and Contract Review Process G5546.

5.3 Quality Policy

SDIX Business Management Team ensures that the quality policy is communicated to all employees. It is included in the employee training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within the organization. This policy:

a.) is appropriate to the purpose of the organization,

b.) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,

c.) provides a framework for establishing and reviewing quality objectives,

d.) is communicated and understood within the organization, and

e.) is reviewed for continuing suitability.

The SDIX Quality Policy is:

At SDIX, management is committed to consistently meeting or exceeding customer expectations by:

- Delivering quality products and services that conform to customer and regulatory requirements.
- Maintaining an effective Quality Management System.

- Providing courteous, knowledgeable, and timely support.

We are a biotechnology organization that continuously improves our processes to ensure our name is synonymous with the highest standards for customer satisfaction and loyalty.

5.4 Planning

5.4.1 Quality Objectives

SDIX Business Management Team ensures that quality objectives, including those needed to meet applicable regulatory requirements and product requirements, are established at relevant functions and levels in the organization. Quality objectives are established to support the organization's commitment and efforts in achieving our quality policy and reviewed semi-annually for suitability. The quality objectives are measurable and consistent with the quality policy. They are reviewed against performance goals at each management review meeting and communicated throughout the organization. Quality objectives are established to support the organization's commitment and efforts in achieving our quality policy and reviewed for suitability.

5.4.2 Quality Management System Planning

The SDIX Vice President & General Manager and Business Management Team have identified, planned and provided the resources needed to achieve the quality objectives and ensure the effectiveness of the QMS. SDIX High Level Processes Flow Chart, FC 4.1.2.1 represents an overview of the SDIX Quality Plan.

SDIX Business Management Team ensures that:

a) The planning of the quality system is carried out in order to meet the requirements of 4.1 of the ISO 13485:2016 standard, as well as the quality objectives;

b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

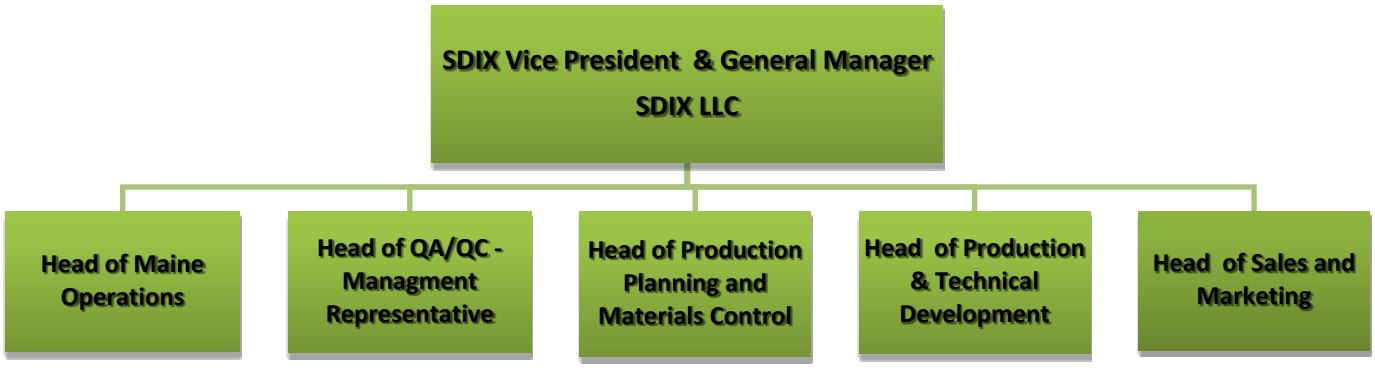
5.5.1 Responsibility and Authority

SDIX Business Management Team ensures that responsibilities are defined, documented and communicated within the organization.

SDIX Business Management Team documents the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of key positions. Quality System SOPs, job descriptions and the organizational chart are reviewed and approved by Management. The SDIX Organizational Chart Summary, FC 5.5.1 represents an overview of the interactions of personnel.

FC 5.5.1 SDIX Organization Chart Summary



5.5.2 Management Representative

The SDIX Vice President & General Manager has appointed the Head of Quality Assurance & Quality Control as the management representative. As management representative, irrespective of other responsibilities, he or she has the following responsibilities and authority that includes:

a. ensuring that processes needed for the quality management system are documented;
b. reporting to Business Management Team on the performance of the quality management system and any need for improvement.
c. ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.5.3 Internal Communication

SDIX Business Management Team has created appropriate processes to ensure communication among its various levels and functions regarding the effectiveness of the quality management system. Communication is conducted by many methods, including but not limited to: All Hands Meetings, Operations Meetings, Weekly Production Meetings, Business Management Team Meetings, e-mail notifications and bulletin boards.

5.6 Management Review

5.6.1 General

SDIX has documented the procedures for management review according to Management Responsibilities and QMS Review SOP G5505. The SDIX Business Management Team (i.e. Top Management) has documented planned intervals to review the QMS annually (at a minimum) at management review meetings. This review assesses the opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records are maintained for each management review meeting.

5.6.2 Review Input

Inputs to management review shall include but is not limited to, information arising from the following:

a. feedback;
b. complaint handling;
c. reporting to regulatory authorities
d. audits
e. monitoring and measurement of processes;
f. monitoring and measurement of product;
g. corrective actions;
h. preventive actions;
i. follow-up actions from previous management reviews
j. changes that could affect the QMS and
k. recommendations for improvement
l. new or revised regulatory requirements

5.6.3 Review Output

The output from the management review shall be recorded and include the input reviewed and any decisions and actions related to:

a. improvements needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes;
b. improvement of product related to customer requirements;
c. changes needed to respond to applicable new or revised regulatory requirements, and
d. resource needs

Results of management reviews are recorded and maintained according to procedure Management Responsibilities and QMS Review SOP G5505.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

The vice president working with the SDIX Business Management Team reviews resource needs, as required. SDIX shall determine and provide the resources needed to maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting regulatory and customer requirements.

6.2 Human Resources

SDIX personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

SDIX documents the process for establishing competence, providing needed training, and ensuring awareness of personnel as per Training System SOP G5551.

SDIX shall:

a) determine the necessary competence for personnel performing work affecting product quality;
b) provide training or take other actions to achieve or maintain the necessary competence;
c) evaluate the effectiveness of the action taken;
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and
e) maintain appropriate records of education, training, skills, and experience.

Note: The method used to assess competency (check training effectiveness) is proportionate to the risk associated with work for which the training or other action is being provided.

6.3 Infrastructure

SDIX documents the requirements for the infrastructure needed to achieve conformity to product requirements, preventing product mix-up and ensuring orderly handling of product (refer to Manufacturing Product Segregation Procedures G5503). Infrastructure includes, as appropriate:

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software) and
c) supporting services (such as transport, communication, or information systems)

The process to prevent product mix-up and ensure orderly handling of product is documented in Manufacturing Product Segregation Procedures G5503.

The organization shall document requirements for maintenance activities, including interval or performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. Records of such maintenance shall be maintained. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring of the equipment.

The following SOPs are included: Manufacturing Product Segregation Procedures G5503, G5507 Equipment Control System, G5526 Record Control Policy, G1155 Animal Facility Heating,

Ventilation and Air Conditioning System (HVAC), G1144 Pest Control Monitoring Program: Delaware , G2322 Pest Control: Maine, G1128 Operation, Maintenance and Monitoring of Emergency Backup Generators, G2227 Generator Operation and Testing: Maine, G5505 Management Responsibilities and QMS Review, equipment-specific SOPs.

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

The SDIX Business Management Team documents requirements for the work environment to achieve conformity to product requirements.

If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instruction to monitor and control these work environment conditions.

SDIX shall:

a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect product safety or performance.
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

SDIX has created a work environment to achieve product conformity. This is documented in the following SOPs, but not limited to:

Gowning Requirements for GMP Sites SOP G5831, General Cleaning and Disinfection Procedure SOP G5829, Daily Cleaning Lab Work Surfaces SOP G2239, Ascites Production Facility Cleaning SOP G1142, Management Responsibilities and QMS Review SOP G5505, Temperature Monitoring SOP G0035, Environmental Monitoring SOP G0055, Temperature Monitoring SOP G2282, Pest Control Monitoring SOP G1144, Pest Control: Maine G2322, Animal Facility Heating, Ventilation, And Air Conditioning System (HVAC) G1155, and Operation, Maintenance and Monitoring of Emergency Backup Generators G1128, Generator Operation and Testing: Maine G2227

6.4.2 Contamination Control

As appropriate, SDIX shall plan special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of work environment, personnel, or product.

SDIX does not manufacture sterile medical devices.

SDIX has created a work environment to achieve contamination control. This is documented in the following SOPs, but not limited to:

Gowning Requirements for GMP Sites SOP G5831, General Cleaning and Disinfection Procedure SOP G5829, Daily Cleaning Lab Work Surfaces SOP G2239, Ascites Production Facility Cleaning SOP G1142, G4402 Packing and Shipping of Final Antibody Product, G0023 Cell Culture Contamination Control Procedure

7.0 PRODUCT REALIZATION

7.1 Planning of Realization Processes

SDIX shall plan and develop the processes needed for product realization. Planning of product realization processes shall be consistent with the requirements of other processes of SDIX's quality management system. It is documented in forms suitable for SDIX's method and areas of operation.

SDIX has established procedures to assess and record risk management throughout product realization according to SOP G5832 Risk Management Process and G5513 Document Control SOP.

In planning the processes for realization of products SDIX has determined the following, as appropriate:

a) quality objectives for the product, project or contract;
b) the need to establish processes and documents, and to provide resources specific to the product, including infrastructure and work environment;
c) verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements

The output of this planning is documented in a form that is suitable for SDIX's method of operations. Documentation that describes how the processes of the quality management system are applied for a specific product, project or contract can be referred to as a quality plan and follow procedure for the Design Check Process SOP G5613 and/or Order Fulfillment and Contract Review Process G5546, and product batch records.

7.2 Customer-related Processes

7.2.1 Determination of requirements related to the product

SDIX determines:

a) requirements specified by the customer, including the requirements for delivery and post delivery activities;
b) requirements not stated by the customer but necessary for specified or intended use, where known;

c) applicable regulatory requirements related to the product, and
d) any user training needed to ensure specified performance an safe use of the product
e) any additional requirements considered necessary by the organization.

Reviews of customer specifications are performed when received and any requirements documented for implementation according to procedure Order Fulfillment and Contract Review Process G5546, and Production Planning for Delaware SOP G5616 and Polyclonal Scheduling G2428. User training needs would be assessed according to The DesignCheck Process G5613.

7.2.2 Review of Requirements Related to the Product

SDIX reviews requirements related to product. In order to establish and maintain customer satisfaction, a formal system is in place and maintained to ensure that each commitment to supply a product is reviewed and controlled. The review is conducted prior to the commitment to supply a product and ensures that:

a. product requirements are defined and documented;
b. contract or order requirements differing from those previously expressed are resolved, and the order requirements are confirmed verbally before acceptance;
c. applicable regulatory requirements are met;
d. Any user training identified is available or planned to be available;
e. SDIX has the ability to meet the defined requirements

When a customer does not provide a documented statement of requirement, the customer requirements shall be confirmed before acceptance (or refer to internal specifications).

Where product requirements are changed, SDIX ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Record requirements from these reviews are shown on the quote, purchase orders, sales orders, contract, e-mails, and/or the order acknowledgement according to procedure Order Fulfillment and Contract Review Process SOP G5546 and Production Planning for Delaware G5616 and Polyclonal Scheduling G2428. User training needs would be assessed according to The DesignCheck Process G5613.

7.2.3 Customer Communication

SDIX recognizes the necessity for customer communication and feedback as a major contributing element of customer satisfaction and has implemented an effective process for communicating with customers. SDIX plans and documents arrangements for communicating with customers in relation to:

a. Product information: SDIX produces hard copy data sheets, Certificate of Analysis, MSDS, and product inserts for products (as appropriate);
b. Inquiries, contracts or order handling, including amendments: SDIX maintains a contacts or order handling, including amendments according to Order Fulfillment and Contract Review Process SOP G5546;

c. Customer Feedback, including complaints: Customers can contact SDIX via phone, website, e-mail, fax, mail and schedule project management meetings, as deemed necessary. Customer complaints are handled according to procedure Customer Complaint Handling and Feedback SOP G5509. Return Material authorization procedure is conducted according to Product Return Material Authorization SOP G4679;
d. Advisory notices will be issued and maintained, as applicable, as per Control of Nonconforming Product G5539.

SDIX shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

7.3 Design and Development

7.3.1 General:

The products and services provided by SDIX which are "For further manufacturing" (i.e. OEM, Contract Manufacturing, Fee for Service) and "for Research Use Only" are excluded from Design and Development (7.3). SDIX does perform Design & Development for SDIX registered product (e.g. IVD and CE marked Products). The Design & Development Process is documented in the Design Check Process SOP G5613.

7.3.2 Design & Development Planning

SDIX plans and controls the Design & Development of products as per Design Check Process SOP G5613. As appropriate, design and development planning documents (DesignCheck record) is maintained and updated as the design and development progresses.

During design and development planning, the organization shall document:

a) design and development stages;
b) review(s) needed at each design and development stage;
c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;
d) responsibilities and authorities for design and development;
e) the methods to ensure traceability of design and development outputs to design and development inputs;
f) the resources needed, including necessary competence of personnel.

SDIX manages the interfaces between different groups involved in Design & Development process to ensure effective communication and clear assignment of responsibility and authority. The planning records shall be updated, as appropriate, as the design and development planning progresses.

7.3.3 Design & Development Inputs

Inputs relating to product requirements are determined and records are maintained. Inputs include, but are not limited to:

a) functional, performance, usability, and safety requirements, according to the intended use;
b) applicable regulatory requirements, and standards;
c) applicable output(s) of risk management;
d) as appropriate, information derived from previous similar designs;
e) other requirements essential for design and development of the product and processes.

The inputs are reviewed for adequacy and approved, with requirements being complete, unambiguous, able to be verified or validated, and not in conflict with each other.

7.3.4 Design & Development Outputs

The outputs of Design & Development are provided in a form suitable for verification against the Design & Development inputs and are reviewed and approved according to the Design Check Process SOP G5613.

SDIX Design & Development outputs:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

The records of design and development outputs are maintained according to the Design Check Process SOP G5613.

7.3.5 Design & Development Review

SDIX at suitable stages (i.e. Gates) performs systematic reviews of Design and Development with documented and planned arrangements as specified in the Design Check Process SOP G5613.

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify and propose necessary actions

Reviews shall involve representatives from different functions within SDIX that are concerned with the applicable design and development stage being reviewed.

Records of the results of the reviews and any necessary action are maintained as specified the Design Check Process SOP G5613. Review records shall include identification of the design under review, the participants involved, and review date.

7.3.6 Design & Development Verification

Verification is performed in accordance with planned and documented arrangements to ensure that the Design & Development outputs have met the Design & Development input requirements.

Verification plans shall be documented and include methods, acceptance criteria and, as appropriate, statistical techniques with rational for sample size.

If the intended use requires the product to be connected with or have interface with another medical device(s) verification shall include confirmation that the outputs meet the inputs when connected/interfaced: Not applicable

Records of the result and conclusions of the verification and any necessary actions are maintained.

7.3.7 Design & Development Validation

Design & Development validation are performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Validation plans shall be documented and include methods, acceptance criteria and, as appropriate, statistical techniques with rational for sample size.

Validations shall be conducted on representative product. Representative product includes initial production units, batches (lots), or their equivalents. The rationale for the choice of product used for validation shall be recorded.

Clinical evaluations and/or evaluation of performance of a medical device (i.e. IHC antibodies) will be evaluated according to national or regional regulations, when applicable, and will not be considered to be released for use to the customer. Note: this evaluation is not required for antibodies used for research or further manufacturing.

Validation will be completed prior to final release for use of product by the customer (the final product delivery or commercial introduction of the product (i.e. samples and/or prototypes may be evaluated by potential customers during the development process)).

Records of the result and conclusion of validation and any necessary actions are maintained as specified in the Design Check Process SOP G5613.

7.3.8 Design and Development Transfer

Design & Development Transfer are described in the Design Check Process SOP G5613 and describes the process for transferring design and development outputs to manufacturing. The Design Check process ensures that the outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Results and conclusions of the transfer are recorded as per G5613.

7.3.9 Control of Design & Development Changes

Design & Development changes are identified and records maintained as per the Design Check Process SOP G5613. SDIX determines the significance of the change to function, performance, usability, safety, and applicable regulatory requirements for the product and its intended use. The changes are reviewed, verified and validated, as appropriate and approved before implementation. The review of Design & Development changes includes evaluation of the effects of the changes on constituent parts and product already delivered, as appropriate.

7.3.10 Design and Development Files

SDIX maintains a Design Check file for each project (product type or product family). The file includes or references records generated to demonstrate conformity to requirements (see G5613 for examples) and design change records.

7.4 Purchasing

7.4.1 Purchasing Process

SDIX has a process to ensure that purchased product conforms to specified purchase requirements as specified in Purchasing, Receiving and Raw Materials Quality System SOP G5521, Supplier Quality System SOP G5516 and Internal Audit System SOP G5519.

SDIX defines criteria for evaluation and selection of suppliers as per Supplier Quality System SOP G5516 and is based on the following:

a) supplier's ability to provide product that meets SDIX's requirements;
b) performance of the supplier;
c) the effect of the purchased product on the quality of product;
d) proportionate to risk associated with the product.

SDIX monitors and re-evaluates suppliers as per Supplier Quality System SOP G5516. Supplier performance in meeting requirements for purchased product shall be monitored as per Supplier Quality System SOP G5516 and Purchasing, Receiving and Raw Materials Quality System SOP G5521 (RMSRs). The results of the monitoring shall provide input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements as per Supplier Quality System SOP G5516.

Records of the results of evaluations, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions shall be maintained according to Supplier Quality System SOP G5516.

7.4.2 Purchasing Information

Purchasing documents (i.e. PO - purchase order, RMSR – Raw Material Specification Receipt) contain information describing or referencing the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of personnel;
d) quality management system requirements;

Purchasing, or their designee, ensures the adequacy of specified requirements contained in the purchasing documents prior to their release according to the procedure Purchasing, Receiving and Raw Materials Quality System SOP G5521.

Purchasing information shall include, as applicable, a written agreement that the supplier notify SDIX of change in purchased product prior to implementation of changes that affect the ability of the purchased product to meet specified purchase requirements as per Supplier Quality System SOP G5516.

To the extent required for traceability, SDIX shall maintain relevant purchasing in the form of documents and records as per Purchasing, Receiving and Raw Materials Quality System SOP G5521.

7.4.3 Verification of Purchased Products

SDIX establishes and implements inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of the verification activities are based on the supplier evaluation results and are proportionate to the risks associated with the purchased product as per Supplier Quality System SOP G5516 and Purchasing, Receiving and Raw Materials Quality System SOP G5521.

When SDIX becomes aware of any changes to purchased product, a determination is made as to whether these changes will affect production or product as per Supplier Quality System SOP G5516.

When SDIX, or one of its customers, proposes to perform verification activities at the supplier's premises, SDIX shall state the intended verification activities and method of product release in the purchasing information.

Records of the verification are maintained according to Purchasing, Receiving and Raw Materials Quality System SOP G5521.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

SDIX plans, carries out, monitors, and controls production and service operations to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to:

a) documentation of procedures and methods for the control of production,
b) qualification of infrastructure,
c) the implementation of monitoring and measurement of process parameters and product characteristics,
d) the availability and use of measuring and monitoring equipment,
e) the implementation of defined operations for labeling and packaging
f) the implementation of product release, delivery and post-delivery activities

SDIX has established and maintained a record for each batch (i.e. Lot) of product that provides traceability and identified the amount manufactured and approved for distribution. The batch (i.e. lot) records are verified and approved according to Lot Record Review Process G5518 and Assessment of Final Product (ME) G2423.

7.5.2 Cleanliness of product and contamination Control

SDIX has established documented requirements for cleanliness or contamination control according to General Cleaning and Disinfection Procedure G5829, Gowning Requirements for cGMP Sites G5831, Daily Cleaning Lab Work Surfaces G2239 and specific manufacturing procedures, if**:**

a) product is cleaned by the organization prior to sterilization and/or its use, or
b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or
c) Product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use, or
d) product is supplied to be non-sterile and its cleanliness is of significance in use, or
e) process agents are to removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

7.5.3 Installation Activities

Not Applicable

7.5.4 Servicing Activities

Not Applicable

7.5.5 Particular requirements for sterile medical devices

Not Applicable

7.5.6 Validation of processes for production and service provision

SDIX validates processes for production and service provision, including software, where the resulting output cannot be or is not verified by subsequent monitoring or measurement, and as a consequence, deficiencies become apparent only after product is in use or service has been delivered. Validation is performed, and records maintained, as per the Validation Master Plan SOP G5807.

Validation shall demonstrate the ability of these processes to achieve planned results consistently.

SDIX documents procedures for validation (Validation Master Plan SOP G5807), as per the following:

a) defined criteria for review and approval of the processes,
b) equipment qualification and qualification of personnel,
c) use of specific methods, procedures, and acceptance criteria,
d) as appropriate, statistical techniques with rationale for sample sizes,
e) requirements for records, and
f) revalidation, including criteria for revalidation
g) approval of changes to the processes.

SDIX documents procedures for software validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to software or its application and will be proportionate to risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation, as well as any necessary actions, shall be maintained per the Validation Master Plan SOP G5807.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

Not applicable

7.5.8 Identification

SDIX documents procedures for product identification and identifies product by suitable means throughout production, as per Identification and Traceability SOP G5801.

SDIX identifies product status with respect to monitoring and measurement requirements throughout product realization. SDIX has established a documented procedure to ensure product status is identified throughout the production and storage to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched or used according to Material Disposition Status and Control SOP G5806. Installation and servicing are not applicable.

A unique lot number is assigned to product as per Identification and Traceability SOP G5801.

Product returned to SDIX are identified and distinguished from conforming product by the following SOPs: Material Disposition Status and Control G5806, and Product Return Material Authorization SOP G4679.

7.5.9 Traceability

7.5.9.1 General

SDIX has established a documented procedure for traceability: Identification and Traceability SOP G5801. This SOP defines the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.

7.5.9.2 Particular requirements for implantable medical devices.

Not Applicable

7.5.10 Customer Property

Care will be exercised while customer property is under control or being used by SDIX. SDIX will identify, verify, protect and safeguard customer property provided for use or incorporation into the product (when applicable) while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it will be reported to the customer in accordance with Receipt, Record and Usage of Customer Supplied Material SOP G5529 and/or Procedure for Antigen Receiving G2272. Records of such activity are maintained.

7.5.11 Preservation of Product

SDIX preserves product conformity of product to requirements during processing, storage, handling, and distribution and applies to the constituent parts of a product, when applicable. This is documented according to Handling, Storage, and Distribution SOP G5803 and manufacturing procedures.

SDIX protects product from alteration, contamination or damage when exposed to expected conditions and hazard during processing, storage, handling and distribution by:

a) designing and constructing suitable packaging and shipping containers;
b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they are controlled and recorded. Product is packaged in suitable containers and any requirements for special conditions is noted in the Sales Order. The product is shipped as per Packing and Shipping of Final Antibody Product G4402.

7.6 Control of Monitoring and Measuring Equipment

SDIX determines the measuring and monitoring to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

This is documented according to Equipment Control System SOP G5507, Equipment, Preventative Maintenance, Malfunction and Failure SOP G5833 and specific equipment SOPs to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification is recorded;
b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded;
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage;

SDIX performs calibration or verification in accordance with Equipment Control System SOP G5507.

SDIX assesses and records the validity of previous measuring results when the equipment is found to not conform to requirements. SDIX shall take appropriate action in regard to the equipment and any product affected (i.e. correction, corrective action).

Records of calibration and verification are maintained as per Equipment Control System SOP G5507.

SDIX documents procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software shall be validated prior to initial use and, as appropriate, after changes to such software or its intended application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. SDIX performs validation processes as per Validation Master Plan G5807.

Records of the results and conclusions of validation and necessary action from the validation shall be maintained as per Validation Master Plan G5807.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

SDIX defines a plan and implements the monitoring, measurement, analysis and improvement processes needed to:

a) to demonstrate conformity of the product
b) to ensure conformity of the quality management system, and
c) to maintain the effectiveness of the quality management system

This includes the determination of appropriate methods, including statistical techniques, and the extent of their use.

8.2 Measurement and Monitoring

8.2.1 Feedback

SDIX gathers and monitors information relating to whether the organization has met customer requirements as one of the measurements of the quality management system. The methods for obtaining and using this information are documented as per:

Capturing Customer Complaints as defined in Customer Complaint Handling and Feedback SOP G5509
Capturing Customer Feedback as defined in Customer Complaint Handling and Feedback SOP G5509
Processing Customer Returns as specified in Product Return Material Authorization G4679
Customer Audits according to G5504 and Inspections by Regulatory Organizations according to G5506
Monitoring post-production activities according to the Design Check G5613 and Risk Management Process G5832.

Procedures for the feedback process are documented as per Customer Complaint Handling and Feedback SOP G5509 and includes provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as product realization or improvement processes according to the procedure Management Responsibilities and QMS Review SOP G5505.

8.2.2 Complaint Handling

SDIX documents the procedure for timely complaint handling in accordance with applicable regulatory requirements as per Customer Complaint Handling and Feedback SOP G5509.

The procedure includes requirements and responsibilities for:

a) receiving and recording information,
b) evaluation information to determine if the feedback constitutes a complaint,
c) investigating complaints,
d) determining the need to report the information to the appropriate regulatory authorities,
e) handling of complaint-related product,

f) determining the need to initiate corrections or corrective actions.

Justification is documented for any complaints that are not investigated. Corrections and corrective actions resulting from a complaint are documented as per Corrective Actions and Preventive Actions SOP G5538.

If investigation determines that activities outside of SDIX contributed to the complaint, relevant information shall be exchanged between SDIX and the external party involved.

Complaint records are documented as per Customer Complaint Handling and Feedback SOP G5509.

8.2.3 Reporting to Regulatory Authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or of advisory notices, the Head of Quality and the Vice President & General Manager of SDIX are responsible for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained with QA. See Customer Complaint Handling and Feedback SOP G5509

8.2.4 Internal Audit

SDIX conducts internal audits at planned intervals to determine whether the quality management system:

a) conforms to the requirements of ISO 13485:2016, SDIX SOPs, FDA Part 820 and other standards/regulations, as applicable, and the quality management system requirements established by SDIX,
b) Is effectively implemented and maintained.

Internal Audit System SOP G5519 defines the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

SDIX plans the audit program, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods are defined and recorded. The selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Audits are conducted by personnel other than those who perform the activity being audited.

Audit records and results and results are maintained, including identification of the processes and areas audited.

Management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their

causes. Follow-up activities include the verification of actions taken and the reporting of verification results.

8.2.5 Measurement and Monitoring of Processes

SDIX applies suitable methods for monitoring and as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate. Refer to SOP G5505 Management Responsibilities and QMS Review and Corrective Actions and Preventive Actions SOP G5538.

8.2.6 Monitoring and Measurement of Product

SDIX measures and monitors the characteristics of the product to verify that product requirements have been met. This is carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria is documented and maintained. Records indicate the identity of the person authorizing the release of the product as per Lot Record Review Process SOP G5518. Records identify test equipment used to perform measurement activities (see Document Control SOP G5513).

Product release and service delivery to the customer will not proceed until all the planned and documented arrangements have been satisfactorily completed, unless otherwise approved by the customer and/or contract (e.g. sample evaluations).

SDIX does not manufacture implantable medical devices.

8.3 Control of Nonconforming Product

8.3.1 General

SDIX ensures that product which does not conform to product requirements is identified and controlled to prevent unintended use or delivery. The SOP, Control of Nonconforming Product G5539, defines the controls and related responsibilities and authorities for with the identification, documentation, segregation, evaluation (including the determination of the need for investigation and notification of any external party responsible for the nonconformity) and disposition of nonconforming product.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, and any investigation and the rationally for decisions shall be maintained.

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery

SDIX deals with Nonconforming product detected before delivery by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by taking action to preclude its original intended use or application;
c) by authorizing its use, release or acceptance under concession;

SDIX ensures that nonconforming product is accepted by concession only if justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance of concession and the identity of the person authorizing the concession is maintained according to Control of Nonconforming Product G5539.

8.3.3 Actions in Response to Nonconforming Product Detected After Delivery

When nonconforming product is detected after delivery or use has started, SDIX shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained.

SDIX documents procedures for issuing advisory notices in accordance with applicable regulatory requirements as per Control of Nonconforming Product G5539. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained.

8.3.4 Rework

SDIX documents the rework according to Rework/Reprocessing SOP G5545 and takes into account the potential adverse effect of the rework on the product. Rework procedures shall undergo the same review and approval as the original procedure.

After the completion of rework, product is verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of the result and conclusion of rework are maintained as specified in the Rework/Reprocessing SOP G5545.

8.4 Analysis of Data

SDIX documents procedures to determine, collect, and analyze appropriate data to determine the suitability, adequacy, and effectiveness of the quality management system, including determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of the data shall include data generated as a result of measuring and monitoring and other relevant sources and include, at a minimum, input from:

a) feedback,
b) conformity to product requirements,
c) characteristics and trends of processes, product including opportunities for preventative actions, and
d) suppliers
e) audits

(Note: f) service reports are not applicable)

Records of the result of the analysis of data is maintained according to Management Responsibilities and QMS Review SOP G5505. If the analysis of data shows that the QMS is not suitable, adequate or effective, SDIX shall use the analysis for input for improvement as per G5505.

8.5 Improvement

8.5.1 General

SDIX identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the quality management system, as well as product safety and performance, through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective and preventative actions and management review.

SDIX evaluates opportunities for improvement at Management Review Meetings as per Management Responsibilities and QMS Review SOP G5505. SDIX will issues advisory notices, when applicable and maintain documents according to Document Control SOP G5513. Customer of SDIX must be notified in the event that a recall is issued by SDIX according to Product Recall SOP G5814.

SDIX is required to notify our authorized representative and competent authority for CE marked product recalls according to Product Recall SOP G5814.

SDIX conducts and documents customer complaint investigations according to Customer Complaint Handling and Feedback SOP G5509. If a customer complaint is not followed by corrective and/or preventative actions the reason is authorized and recorded.

8.5.2 Corrective Action

SDIX takes corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective action is to be appropriate to the effect of the nonconformities encountered.

The documented procedure for corrective action is Corrective Actions and Preventive Actions SOP G5538 and defines requirements for the following:

a) reviewing nonconformities (including complaints),
b) determining the causes of nonconformities,
c) evaluating the need for actions to ensure that nonconformities do not recur,
d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation,
e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product,

f) reviewing the corrective action taken and its effectiveness.

Records of any investigation and action taken (corrective actions) are maintained as specified in the Corrective Actions and Preventive Actions SOP G5538.

8.5.3 Preventive Action

SDIX determines preventive action to eliminate the causes of potential nonconformities to order to prevent their occurrence. Preventive actions taken are appropriate to the impact of the potential problems.

The documented procedure for preventive action, Corrective Actions and Preventative Actions SOP G5538, describes requirements for:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation,
d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product,
e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of any investigation and of action taken (preventive actions) are maintained as specified in the Corrective Actions and Preventive Actions SOP G5538.

Please direct all comments, concerns, and recommendations to the:

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9.0 REVISION HISTORY

Summary of Revision	Justification
Corporate Overview – Removal of Sandy Drive Facility in Delaware	Relocation of the Ascites Production Facility from 128 Sandy Drive, Newark Delaware to 52 Anderson Road, Windham Maine
Update to align with formatting and content of ISO 13485:2016	Update to new standard