1.0 Purpose of Procedure

This document is intended to describe the context of the organization of Product Resources and its QMS so that management is able to best guide the company and make informed strategic decisions, and to provide a basis for the design of the QMS and implementation of significant changes to it.

2.0 Scope of Process

The scope is to describe the context of the organization, understand the needs and expectations of interested parties, describe the scope of the QMS, and describe the documented QMS and guidelines for significant changes to it. Management can use this information to communicate to employees, customers, and third parties including registrars and regulatory bodies the context of the organization and the system design. The scope also includes designation of the Management Representative.

3.0 Process Owner(s)

3.1 Chief Quality Officer

3.2 Management

3.3 Quality

3.4 MIS Manager

4.0 Procedure

4.1 Context of the Organization

Product Resources is a product design, engineering and manufacturing company with expertise in designing and building complex scientific and industrial equipment. Product Resources principal business activity is the engineering and manufacturing of custom products and assemblies for the pharmaceutical, semi-conductor, life sciences, medical device, and other industries. Product Resources brings a highly technical and multi-disciplined approach to product development outsourcing. Our end-to-end product development solutions ensures seamless transition from design to manufacturing to field support:

- Product design/engineering – prototype development, proof of concept, product testing, regulatory compliance
- Contract manufacturing – complex product assembly and testing, short-to-medium volume
- Post-production services/support – inventory management, replacement parts, maintenance, calibration, repair

See also 91-8001, Infrastructure, for the infrastructure associated with the above.

4.1.1 Issues that can affect the ability for Product Resources to achieve its strategic direction are both internal and external:

- Government regulations and changes in the law
- Economic shifts in the organization's market
- The organization's competition
- Events that may affect corporate image
- Changes in technology
- Corporate funding and resources
- Changes in customers' organizations including mergers and acquisitions and product lifecycle decisions made

4.1.2 The biggest competitors for Product Resources are:

- Other contract manufacturing and engineering companies
- "Insourcing" – a customer or potential customer decides to manufacture in item in house instead of working with a provider such as Product Resources

4.2 Interested Parties

4.2.1 Product Resources has the abilitly to build complex, techinically advanced instruments, devices, and other products. Product deliverables may include products with the following technologies and of the following types:

- Embedded systems
- Controls and automation
- Robotic applications
- Integrated systems
- Electro-mechanical assemblies
- Complex instrumentation
- Electronic systems
- Precision mechanical systems
- Optics
- Pneumatics and fluid control
- Medical devices
- Devices for potentially explosive atmospheres

4.2.2 Product Resources, therefore, has customers and potential customers for the above products and technologies in the pharmaceutical, semiconductor, life sciences, medical device, potentially explosive atmospheres, and other industries that use these technologies. Customers and potential customers are interested parties.

4.2.3 Product Resources relies on a supply chain for standard and custom parts and assemblies. What Product Resources does not manufacture it must purchase, and so suppliers are interested parties.

4.2.4 Product Resources has its QMS audited and registered by accredited third parties. These parties are interested parties.

4.2.5 Product Resources designs and manufactures product that has regulatory testing and sometimes bears the marks of NRTLs and foreign equivalents. These bodies are interested parties.

4.2.6 Product Resources has regulatory requirements depending on customers project

4.3 Scope of the Quality Management System and Excluded and Non-Applicable Elements

The scope of Product Resources' QMS for each of these standards is given here. Excluded and non-applicable elements are also summarized here for organizational context and are expressed in the text of their respective Quality Manuals, where specific elements of the standard are stated as excluded or non-applicable, and justifications are given for non-applicable items.

4.3.1 For ISO 9001 (general applicability):

1. Scope: Design, Development, Manufacture and Service of Custom Instrumentation, Devices, Controls, and Integrated Systems Using Embedded Systems, Electronic, Precision Mechanical, Optical, and Pneumatic Technologies
2. Excluded Elements: Installation is excluded for compliance to this standard. Product Resources does not perform installations.
3. Non-Applicable Elements: None.

4.3.2 For ISO 13485 (for medical devices):

1. Scope: Manufacture and Service of Custom Instrumentation, Robotics, Controls, and Integrated Systems Using Embedded Systems, Electronic, Precision Mechanical, Optical, Pneumatic, and Fluid Technologies for application in the Medical Device Industry.
2. Excluded Elements: Design and development are excluded for compliance to this standard because, for this standard, Product Resources is acting as a contract manufacturer and is not design-responsible. Installation is excluded for compliance to this standard. Product Resources does not perform installations.
3. Non-Applicable Elements: Product Resources does not manufacture or service implantable devices and therefore the special requirements for implantable devices do not apply to our organization. Product Resources does not manufacture or service sterile medical devices and therefore the special requirements for sterile medical devices do not apply to our organization. Last, Product Resources does not have any direct reporting responsibilities to regulatory authorities, as Product Resources is acting as a contract manufacturer and is not directly putting product in the market.

4.4 Quality Management System (QMS) and Its Processes

4.4.1 Product Resources has determined the processes needed for the quality management system and their application throughout the organization. Procedure 91-9003, Processes and Procedures, describes the major processes for Product Resources and the procedures that implement those processes.

4.4.2 Product Resources has designed and documented a QMS compliant to the external standards (“Tier 0”) ISO 9001:2015 and ISO 13485:2016.

Product Resources’ QMS is documented in four tiers:

1. Tier 1 is Quality Manuals. There is one Quality Manual for each external standard. The Quality Manual will mirror the requirements of the external standard and will provide a mapping from external standard to Product Resources’ processes and procedures, the Tier 2, by way of giving forward references to them where they apply.
2. Tier 2 is QMS procedures. Prior to documenting the QMS procedures, the major processes at Product Resources were determined, and the procedures were grouped by process. See 91-9003 for the breakdown. While there are multiple Quality Manuals, there is a single, unified Tier 2.
3. Tier 3 is work instructions and forms related to QMS procedures. Tier 3 is also product-specific work instructions in the form of assembly drawings, assembly procedures, test procedures, scheamtics, and all other types of manufacturing and product documentation.
4. Tier 4 is the records that we keep to demonstrate comformance and to provide a history and traceability.

4.4.3 The documentation for Tiers 0 through 3 can be found in the QMS system and is the responsibility of Document Control. In addition, Document Control keeps in distribution paper binders of Tiers 1 and 2. 91-6001, Control of Documents, appliers to these tiers.

4.4.4 The documentation for Tier 4 is found in the locations described in 91-6002, Control of Records.

4.4.5 Product Resources’ Chief Quality Officer has the responsibility and authority to design and implement this described QMS.

4.4.6 Product Resources’ Chief Quality Officer serves as the Management Representative and is the responsible contact for external parties in matters of regulation and Quality.

4.5 Changes and Upgrades to the Quality Management System (QMS)

This section applies to significant changes to the QMS, and for these purposes we will define a significant QMS change as one that deals with a change of scope for the QMS and/or one that involves an upgrade to new major version of an external standard to which the QMS is to comply.

QMS changes that are less significant than this definition are handled solely as per 91-6001, Control of Documents.

It is assumed as the starting point that Management Review (see also 91-9005) has already made the decision to pursue the significant change. Our requirements for significant changes to the QMS follow:

4.5.1 A project team or committee will be formed. The QA Manager and least one member of management will be on this team. The team has the responsibility of guiding the project and of reporting to management on progress.

4.5.2 The team will identify the tasks and milestones associated with carrying out the change in the form of a plan along with the required resources and responsible parties. So that progress can be tracked and compared with the original plan, the plan will be updated with actual start dates and completion dates, along with the planned start and completion dates.

4.5.3 In the case of upgrades to new major versions of external standards, the Management Review group will be given the opportunity to evaluate the plan and comment on its feasibility, possibly leading to plan changes.

4.5.4 The tasks and milestones of the plan will include scheduling and completing internal audits for changed aspects of the QMS. In the case of upgrades to new major versions of external standards, a full system audit will be completed for readiness for certification by an external party.

4.5.5 The tasks and milestones of the plan will consider and include training requirements, including training needs for understanding new external standards (if applicable) and for awareness and process specific training of the resulting changed QMS.

4.5.6 In the case of upgrades to new major versions of external standards, the Management Review group will be given the opportunity to evaluate readiness for certification by an external party. It will conclude that the QMS is ready for external certification.

4.6 Changes to QMS Software

This section applies to changes to the key software that supports the QMS. For Product Resources this is Infor ERP Business (also known as SyteLine and referred to by Product Resources as SyteLine) and QT9 QMS. As these packages are central to the operation of Product Resources' processes, validation may need to take place upon changes to this software, and a risk-based approach will be taken.

Our requirements for changes to this QMS software follow:

4.6.1 We will trigger this process when a new version is to be deployed. It is also applicable and triggered when we deploy a custom modification.

4.6.2 Next is a decision process that the change requires validation or does not require validation. To document this decision process, we will create a Risk Assessment in QT9 QMS; ref category "Changes to QMS Software". The Risk Assessment will be assigned to the MIS Manager. The extent of the change (ref "Description") will be analyzed; ref "Initial Analysis". After analysis, an "Initial Risk Score" will be assigned on a scale of 1-10 with 1 being the lowest risk and 10 being the highest risk. A risk plan (ref "Risk Plan") will be formulated, and dependening on the initial risk score, one of two approaches will be taken:

4.6.2.1 If the initial risk score is 5 or higher, the risk plan and "Action Taken" will always be to transition from a Risk Assessment to a Change Control in QT9.

4.6.2.2 If the initial risk score is under 5, a Change Control is not required. In this case, the responsible party will document the risk plan, and it will describe what the nature of the validation will be, including the possibility that no validation is required (with the justification).

In both cases, at least two Approvers will be assigned with one of them the MIS Manager and others who are knowledgeable in the applicable software and QMS topics so as to be able to critique the Risk Assessment's analysis and conclusions. The Risk Assessment is submitted for approval, and if a Change Control is not required, this is the end of the process.

4.6.3 When a Change Control is required, a Change Control record is created in QT9; ref category "Changes to QMS Software". The Change Control will be assigned to the MIS Manager. The responsible party then completes an "Initial Analysis", which may be taken from the one completed in the associated Risk Assessment, and determines the impact (ref "Impact Assessment"). This is followed by the creation of a plan (ref "Planning"). The plan will address:

4.6.3.1 Who are the members of the change team (or committee). The MIS Manager will always be on this team. The team has the responsibility of guiding the change, of reporting to management on progress, and of keeping the Change Control updated.
4.6.3.2 The tasks and milestones associated with carrying out the change along with the required resources and responsible parties.
4.6.3.3 The tasks and milestones of the plan will consider and include training requirements, including training needs for use of the new software and awareness needs and any related process specific training for changed QMS processes, as applicable.
4.6.3.4 The tasks and milestones of the plan will consider and include a validation plan and execution of the validation.

So that progress can be tracked and compared with the original plan, the plan will be updated with actual start dates and completion dates (ref "Action Taken"), along with the original planning.

At least two Approvers will be assigned to the Change Control with one of them the MIS Manager and others who are knowledgeable in the applicable software and QMS topics so as to be able to critique the plan completion. The Change Control is submitted for approval. This ends the process.

4.6.4 When validation is required, if the software has the ability to be tested first in a test environment, the use of a test environment is the approach that will be taken. Not all software supports this, however. When its not supported, the change will be made upon some break in business to permit time for testing and time to handle the possibility that the software needs to be rolled back to the pre-change version. In both cases, it will be known that a pre-change backup exists, software and company data, before proceeding with the change.

5.0 Control of Records

The storage location and retention period for records referenced above is given in 91-6002, Control of Records.