PURITAN PRODUCTS

QUALITY OVERVIEW

Quality Management System
Self-Audit

September 15, 2015

Founded in 1987, Puritan Products, Inc. is a cGMP compliant, FDA registered and inspected, and ISO-9001:2008 certified company specializing in high purity chemicals and customized chemical blends. We serve the global pharmaceutical, biopharmaceutical, microelectronics, and laboratory markets. Puritan Products is a highly-responsive supply chain partner committed to quality and total customer satisfaction.

At Puritan Products, continuous improvement is part of our culture and affects constructive changes to our quality system. Our quality management system is assessed during frequent customer and regulatory agency audits and consistently receives positive feedback. These interactions facilitated the preparation of this overview, designed as a self-audit, that will answer many of your questions regarding our quality system from both an ISO and GMP perspective.

Lehigh Valley Industrial Park I | 2290 Avenue A | Bethlehem, PA 18017
(610) 866-4225

PURITAN PRODUCTS

1. Management Responsibility

		Yes	No	N/A
1.1	Is there a procedure(s) for Management Responsibility and Reviews?	X		
1.2	Is there a process by which executive management oversees the integrity of the Quality System when changes are planned and implemented?	X		
1.3	Is there a formal internal audit program with written procedures for Internal Audits?	X		
	GMP internal audit 21CFR211	X		
	ISO 9001:2008	X		
1.4	Is there a process by which results of internal audits are documented and nonconformances are tracked for correction and corrective action?	X		
Comments: Internal audits are performed to meet both GMP and ISO requirements annually.				

2. Quality System

		Yes	No	N/A
2.1	Who is the ISO registrar? **QSR**			
2.2	What is the ISO certification number? **QSR-772**			
2.3	Does the Quality Management System include a Quality Manual and a quality policy?	X		
2.4	Does the Quality Management System include a Quality Policy?	X		
2.5	Is Puritan Products registered with the FDA?	X		
2.5	What is the registration number? **181226655**			
2.6	Has Puritan Products been audited by the FDA?	X		
	If so, when? **September 2011** **June 2015**			
	Any findings reported? **No 483 Reports Issued**			
2.7	Is there a quality procedure/process in place to ensure the quality of goods and/or services?	X		
Comments: Puritan Products has been certified to ISO 9001 since May 2003 and registered with the FDA since January 2010.				

3. Management of Change

		Yes	No	N/A
3.1	Does Puritan Products have a written procedure describing the process to manage changes that may affect customers?	X		
3.2	Will Puritan Products agree to sign a customer MOC Agreement if solicited?	X		
3.3	Is there a list of purposes that would invoke the need for an MOC notification to be sent out to customers?	X		
3.4	Are MOC communications performed at least 30 days prior to implementation of change?	X		
3.5	How are MOC communications sent? **MOC notifications are sent by email**			

Comments: Changes that require customer notification via MOC are:

- the manufacturing process, packaging design, packaging components, materials of construction, raw materials, sourcing, testing methods or instrumentation, or any other change that can substantially affect the efficacy of the finished product, as it relates to safety, identity/integrity, strength/assay, purity, or overall quality (SISPQ).

4. Document Control

		Yes	No	N/A
4.1	Are there written procedures for document controls including record retention, revision, review, and approval?	X		
4.2	Is there a document numbering system that designates each procedure, instruction, form, etc?	X		
4.3	Is there a process for control of specifications?	X		
4.4	Are employees trained prior to revisions of a document taking effect?	X		
4.4	Is each batch record adequately controlled including a review of content and approvals?	X		
4.5	Are there second person verifications required for GMP records?	X		
4.6	Who releases a product upon approval of lab analysis and batch record? **Director of Quality**			
4.7	Are document errors communicated to the person that performed the infraction to ensure proper documentation skills?	X		

Comments:

A batch record includes:

- Production Worksheet, Label Accountability Form, Label Verification Form, Packaging Instructions, In Process Audit Form, Blend Sheet and Traveler(for product blends), Torque and Weight Sheets where applicable, Product Release/Approval Form.

The batch record process flow:

- Completed by Chemical Operator; Laboratory approval; Accounting department obtains data for inventory transactions; Quality Assurance department reviews and initials as correct and complete.
- The Director of Quality performs final review and release of every production batch.

5. Purchasing

		Yes	No	N/A
5.1	Is there a purchasing control process containing written procedures for establishing and maintaining control of purchasing activities?	X		
5.2	Is there a controlled “Approved Vendor List?”	X		
5.3	Is there a Purchase Order program that restricts purchasing to only the vendors on the “Approved Vendor List?”	X		
5.4	Is there a supplier evaluation program?	X		
5.5	Are supplier audits performed?	X		
5.6	Are quality issues communicated to the supplier (SCAR)?	X		
5.7	Are supplier quality issues measured and monitored for trends?	X		
5.8	Is there a process by which written specifications are provided to suppliers for review and approval?	X		
5.9	Are suppliers required to provide notification of changes being made to their manufacturing processes and/or location.	X		
5.10	Is there a process by which incoming materials are assessed for acceptance against a certificate of analysis/compliance, and/or tested for acceptability?	X		
5.11	Are raw materials accepted based upon COA or tested for verification? **All raw materials are sampled and tested**	X		

Comments:
Suppliers are categorized into Tiers based on the criticality of the raw materials that they supply to Puritan Products. Suppliers in Tier 1 are scheduled to be audited at a minimum every 5 years.

6. Product Identification and Traceability

		Yes	No	N/A
6.1	Is there a written procedure(s) for the identification and traceability of product through all stages of receipt, production, and distribution to prevent mix-ups?	X		
6.2	Is there a lot control number that is dedicated to each lot or batch of raw materials and finished product?	X		
6.3	Does every package, production vessel, and equipment contain product designation?	X		
6.4	Is each idle piece of equipment properly labeled as “cleaned” or “needs to be cleaned?”	X		
6.5	Are products associated with quality issues properly tagged as being quarantined or rejected?	X		

Comments: Lot Number description: 97390021301

- 9739- Product code
- 002- Julian Date
- 13- Year
- 01- Sequential Number

PURITAN PRODUCTS

7. Production and Process Control

		Yes	No	N/A
7.1	How many production facilities? **One facility located in Bethlehem, Pa**			
7.2	Are there production and process control written procedures to ensure that product quality is maintained and specifications are met?	X		
7.3	Is FIFO (first-in-first-out) employed as a method of rotating stock?	X		
7.4	Is there second person verification during GMP production processes?	X		
7.5	Are there proper environmental control, contamination control, and facility requirements for the products being manufactured?	X		
7.6	Is there a Pest Control program with written procedures?	X		
7.7	Are the pest control chemicals monitored, controlled and documented?	X		
7.8	Is there a program entailing the requirement for “line clearance” both post and pre?	X		
7.9	How is product contamination controlled during production processes?			
	Dedicated equipment?	X		
	Cleaning process?	X		
7.10	Is the proper safety equipment (PPE) communicated to the persons handling chemicals?	X		
7.11	Are there procedure(s) to ensure that equipment is maintained, calibrated, qualified, and/or validated appropriately?	X		
7.12	Are NIST Standards utilized where necessary?	X		
7.13	Are photos utilized when possible to show “best practices?”	X		
7.14	Is there a general housekeeping program?	X		
7.15	Is access to the facility restricted and controlled?	X		
7.16	What size is the facility? **50,000 square feet**			

Comments: Puritan Products utilizes dedicated equipment including filling lines, nozzles, hoses, vessels, carts, etc. When cleaning is necessary, the only cleaning agent utilized is water from our USP water system. No surfactants or solvents are utilized.

8. Inspection and Testing

		Yes	No	N/A
8.1	Are there written procedure(s) for performing incoming, in-process, and final product inspection and testing to verify that the specified requirements for the product are met?	X		
8.2	Is there a procedure(s) to ensure that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements?	X		
8.3	Are there test methods that are standardized, documented, and referenced by applicable quality assurance approved specifications (for in process testing)?	X		
8.4	Is there a calibration program for laboratory equipment?	X		
8.5	Are laboratory notebooks utilized and maintained?	X		
8.6	Are all incoming sample bottles labeled with product, date, operator, and from what location?	X		
8.7	Are NIST traceable standards utilized when possible?	X		
8.8	Are test methods validated where necessary?	X		
8.9	What method is utilized for storing and maintaining QC results?			
	Hard copy, paper printout?	X		
	Electronic? Validated system?		X	
8.10	Is there a program containing a written procedure describing the steps required for material that is out of specification?	X		
8.11	Are tests being performed by lab technicians or chemists? **All lab personnel have a chemistry or biology degree.**			
8.12	Who performs the final review, release, and COA generation? **Lab Manager**			
8.13	Are product retains kept? If so, for how long? **1 year past shelf life**	X		
8.14	Are stability studies being performed?	X		

Comments: Puritan Products utilizes LIMS which is a product of Blaze to manage test results and COA creation. Puritan Products laboratory equipment includes but is not limited to:

- Particle counter, Refractometer, KF Water Titrator, Autotitrator, ICP-OES, ICP-MS, UV-VIS, GC-FID, GC-TCD, FTIR, TOC-L, MP-AES, Atomic absorption spectrometer, and Ion Chromatograph.

9. Control of Inspecting, Measuring and Test Equipment

		Yes	No	N/A
9.1	Is there a written procedure(s) to control, calibrate, inspect, and maintain measuring and test equipment?	X		
9.2	Is there a procedure(s) that requires labeling of equipment to show the calibration status?	X		
9.3	Are calibration records stored in a controlled location and include a unique identifier, calibration dates, and the signature of the individual performing calibration?	X		
9.4	Are calibration standards and references traceable to national standards (NIST)?	X		
9.5	Are calibrations performed internally or by an outside calibration group? **Outside calibration group**			
9.6	Is there a preventive maintenance program in place and documented in a written procedure?	X		
Comments: Calibration "checks" are performed internally by the maintenance department but the official calibration is performed by a certified calibration contractor. Scale "check weights" are also calibrated by the same certified calibration contractor.				

10. Control of Nonconforming Product

		Yes	No	N/A
10.1	Is there a procedure(s) to ensure that products that do not conform to specified requirements are prevented from unintended use or installation	X		
10.2	Is there a program including written procedure(s) that describes the identification of nonconforming products and documentation of nonconformances?	X		
10.3	Is there a procedure(s) for segregation and control of non-conforming product and evaluation of nonconformances (including a determination of the need for investigation)?	X		
10.4	Is there a procedure(s) for disposition and rework of nonconforming product?	X		
10.5	Is there a Material Review Board (MRB) that reviews and decides disposition?	X		
10.6	Are quality issues reviewed and examined regularly for trend analysis?	X		
Comments: None				

11. Corrective and Preventive Action (CAPA)

		Yes	No	N/A
11.1	Are there procedures for investigating a non conformance, implementing corrective and preventive actions (CAPA), and demonstrating that the actions completed are effective?	X		
11.2	Is there a CAPA process that includes written procedures for data analysis, communication to those who are directly responsible for the quality of the product, investigations, root cause analysis, identification of corrective actions/preventive actions, verification of corrective and preventive action effectiveness?	X		
11.3	Do quality issues requiring CAPA get communicated during the Management Review meeting?	X		
11.4	Is there a written procedure for product recall?	X		
11.5	Have there been any drug product recalls in the last 4 years?		X	
Comments: Quality issues are documented in one of three methods: Supplier Quality Issues, Internal Quality Issues, Customer Quality Issues				

12. Handling, Storage, Packaging and Delivery

		Yes	No	N/A
12.1	Is there a procedure(s) for controlling the handling, storage, packaging, labelling, preservation, and distribution of materials and product?	X		
12.2	Is there a procedure(s) to prevent material/product mix-ups, damage, deterioration, theft, contamination or other adverse effects?	X		
12.3	Is there a procedure(s) for the control of delivery and distribution to ensure that only products approved for release are distributed and that distribution records are maintained?	X		
12.4	Does Puritan Product utilize an electronic warehouse inventory management system?	X		
12.5	Is there a procedure(s) that provides methods of preservation and separation of materials and product while it is under your company's control?	X		
Comments: None				

13. Control of Quality Records

		Yes	No	N/A
13.1	Is there a process by which quality records are maintained and controlled to provide evidence of conformity to requirements and the effective operation of your company's quality management system?	X		
13.2	Is there a record retention process with requirements including storage, control, and maintenance of all controlled documents and records?	X		
13.3	How long are quality records maintained and available for review? **5 years**			
Comments: All quality records are stored, controlled, and maintained at the facility.				

14. Training

		Yes	No	N/A
14.1	Is there an employee training program with written procedures for employee training, including documented training requirements for each job function?	X		
14.2	Is there a procedure(s) for the maintenance of training records?	X		
14.3	Is there a maintenance department training and competence program?	X		
14.4	Is cGMP training performed at a minimum of 1/year for all employees?	X		
14.5	Are consultants, who are hired to advise on any aspect of manufacturing, packaging, processing, and release asked to provide evidence of their education, training, and experience?	X		
Comments: Puritan Products utilizes a Skills Based Work System to manage and maintain the training process for Chemical Operators.				

15. Material Control

		Yes	No	N/A
15.1	Is there a procedure(s) for material control including traceability, where required and distributions controls?	X		
15.2	Is there a process by which your production area maintains records for all products throughout the manufacturing process?	X		
15.3	How is material and inventory tracked in the warehouse?			
	Electronic Control?	X		
	Physical control through labeling?	X		
15.4	Are all raw materials, production vessels, and finished products stored inside under protection of roof?	X		
15.5	Is there a written procedure(s) and quarantine location for material that is reported as having a quality issue and/or out of specification?	X		
Comments: Puritan Products utilizes barcode labeling on each package and scan guns to verify that the product that is being "picked" is the correct product and also to see if the product has been QA released.				

16. Labeling and Packaging Control

		Yes	No	N/A
16.1	Is there a procedure(s) for controlling the handling storage and preservation of packaging and labelling components?	X		
16.2	Is there a procedure(s) for electronic file maintenance?	X		
16.3	Is there a system for inspection of printed labels?	X		
16.4	Is there a system for accountability, verification, and control of labels with preprinted lot numbers and/or expiration dates?	X		
16.5	Is the label storage area restricted to authorized personnel only?	X		
Comments: Puritan Products prints all product labels in house except for private label customers which have the option of sending preprinted labels. Lot numbers and all product information are printed on the labels at the time of printing the label which occurs within 3 days of the production of that batch.				

17. Validation/Qualification

		Yes	No	N/A
17.1	Does Puritan Products have a Master Validation Plan for manufacturing and laboratory operations?	X		
17.2	Does Puritan Products conduct equipment validation including installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ) where applicable?	X		
17.3	Does Puritan Products conduct testing method qualification or validation, as applicable?	X		
17.4	Does Puritan Products conduct non-Product Software validation including the requirements of 21 CFR, Part 11, as applicable?			X
17.5	Does Puritan Products have a validated USP water system?	X		
Comments: None				

18. Staff Levels

Department	Total Staff
Operations (includes Maintenance)	18
Quality; QA & QC	9
Administrative/other	17
Total Staff	44

19. Contact Information

Position/Title	Phone Number
Director of Quality	610-866-4225
Laboratory Manager	610-866-4225

20. Core Competencies

- **GMP Manufacturing**
  - Acids & Acid Dilutions
  - Biological Buffer Salts
  - pH Buffers and Conductivity Stds
  - Salts
  - Sodium Hydroxide Solutions
- **Custom Chemical Blending Expertise**
  - Acid Solutions
  - Base Solutions
  - Salt/Buffer Solutions
  - Solvent Blends & Solutions
  - Acid/Solvent Blends
  - Solvent/Solvent Blends
- **High purity acids, bases, and solvents**
  - ACS
  - SEMI
  - USP
- **Contract Manufacturing**
  - Proprietary Customer Formulations
- **Custom Packaging/Unit Dose**
- **Private Labeling**
- **In-house design and construction of patented, specialized processing systems**

21. Revision History

Rev.0 – Effective January 2013
Rev.1- Effective July 20, 2015
Rev.2- Effective September 15, 2015

Director of Quality-Author