Laysan Bio Inc.

Differences between Compliant Manufactured Product And Catalog Grade Product

Producing compounds under cGMP regulations is a more costly process compared to Laysan's catalog grade products. Laysan is not able to tell you if you require cGMP or Catalog grade product, that determination is to be made by the end user of our products. Though most companies choose to use cGMP grade product in their drug products or medical devices, it is not necessarily required. Catalog grade product may be used in pharmaceutical applications and in medical devices, but there are more expectations on the end user to fully characterize the catalog grade product. Thus, most companies decide to take the option with less risk and require their PEG reagent to be made under cGMP regulations. We hope this information will help you determine whether you can use Catalog or cGMP grade products in your program.

cGMP Grade Products: "Compliant Manufactured"

- All standard operating procedures (SOP), manufacturing instructions, test methods, and Quality Assurance (QA) procedures are written and pre-approved before use.
- QA controls all documents and issues batch production records for each batch of product manufactured.
- QA reviews all the completed manufacturing and analytical testing documentation prior to release of any final product.
- Each product has pre-approved and documented specifications and release criteria.
- Manufacturing and Analytical Testing is performed by trained employees, and training documentation is kept for each employee.
- Two operators participate in all manufacturing steps in the batch record: one for performing each step and the other confirming the step as the "checker."
- Laboratories used for manufacturing are used for a single product at a time, are cleaned according to pre-approved cleaning procedures, and are inspected by QA before being released for use for the next batch of product.
- All equipment is qualified, maintained and/or calibrated according to pre-approved SOP.
- All equipment & glassware have unique identification numbers and a clean and use log for tracking purposes.
- All raw materials are received under pre-approved documentation, are tested by pre-determined analytical methods and must pass pre-determined specifications before they are released for use in manufacturing.

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- All raw materials are issued a unique lot number for traceability, and documentation for each lot is kept for a minimum of three years after the consumption of the material.
- Packaging is performed in a validated environment to ensure a controlled and consistent process.
- Retain samples are packaged for each batch of product and are controlled by QA.
- Analytical methods used for the release of final product are qualified at a minimum and are validated prior to process validation.
- Cleaning procedures are validated during process validation.
- QA controls the storage, distribution and shipping of all final products according to pre-approved SOP.
- Prospective stability studies are performed on products which have process validation.
- QA routinely performs internal quality audits and continually improves our quality system.
- Laysan supports customer quality audits every 12 months or more.

Catalog Grade Products: "Research-Grade"

- Products may be manufactured in lab with multiple other products at the same time.
- Final product testing is performed using a minimal amount of non-qualified analytical methods.
- There are no pre-determined formal release specifications for each product.
- Certificate of analysis are completed and released by the analytical group and is not reviewed by QA.
- The production and testing of product is not controlled by the Laysan Quality System.
- Manufacturing documentation is recorded into a laboratory notebook by the chemist performing the work.
- A single chemist performs the processing of the final product.
- There are no pre-approved operating procedures nor pre-approved manufacturing instructions.
- Only PEG raw materials are tracked during processing.
- There is no testing and release of raw materials used for production.
- No stability studies are performed on final products.
- Retain samples are kept until the lot is depleted.

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