8.15
Mock Recall

8.15.1
The mock recall procedure shall be performed once per year as part of the internal audit program. This is in order to test the process and ensure that if an issue arises with any product, Polypeptide can rapidly identify and remove the product from the supply chain

Note: This mock recall should occur only if there was no initiation of a live recall in that year

8.15.2 Based on industry best practices and regulatory requirements, the following documentation should be considered (at a minimum) when conducting a mock recall of active pharmaceutical ingredients: Form-106, Out of Specification Report, Form-040, Customer Complaint Form and Form-286, Recall of Active Pharmaceutical Ingredients. A Root Cause Investigation may be required to determine/clarify root cause per SOP QA-042, Root Cause Investigation but it is not necessary.

8.15.3
The initiation of the mock recall will begin with the distribution of an email to all relevant personnel involved with the maintenance or distribution of the product. The email will state a condition or situation and that a mock recall will be performed.

8.15.4
The email will give a timeline when the mock recall will start and a tentative date of its conclusion.

8.15.5
Identifying the recalled products: The products that will be included in the mock recall should be identified, along with their lot numbers and expiration dates.

8.15.6
Simulating the recall: The mock recall should be simulated by using a scenario that mimics a real recall situation. This can involve contacting customers or vendors, notifying regulatory agencies, and removing the recalled products from the market. (In the form of a dummy email).

8.15.7
Evaluating the mock recall: After the mock recall is complete, the recall team should evaluate the effectiveness of the exercise and identify areas for improvement