Annual Product Review Process for Pharmaceutical Industry – Part One

Applies to:

SAP Service Oriented Architecture (SOA), Business Process Management (BPM), Business Process Expert (BPX) and Life-Sciences Industry Vertical. For more information, visit the Business Process Expert homepage.

Summary

For Life-Sciences Industry, Annual Product Review (APR) is an important part of the overall regulatory compliance process. This article will provide an overview about APR and typical challenges faced by the customers. We also share the experiences from a Collaboration Project between SAP ES Community and Intelligroup, where APR Community Definition Group (CDG) was formed as part of this initiative and multiple work packages were defined and validated by customers as part of this innovation project. We intend to cover this topic in 3 parts and beginning with this as the first one focusing on general overview. The next articles will cover the high level work package descriptions and the use of SAP BPM and other tools to build this composite solution.

Authors: Vinesh Y. and Liladhar Bagad

Company: Intelligroup Inc.

Created on: 22 December 2008

Author Bio

Y Vinesh Balakrishnan is a Domain Expert in Life Sciences, currently working at Intelligroup. He is a business process expert with a proven ability to adopt technology in innovative manner to meet business process requirements and solve business problems, with a sharp focus on execution excellence. He is a member of Enterprise Services Community and currently working on solutions in the areas of Annual Product Review, Validation and A1 Solution for Life Sciences companies.

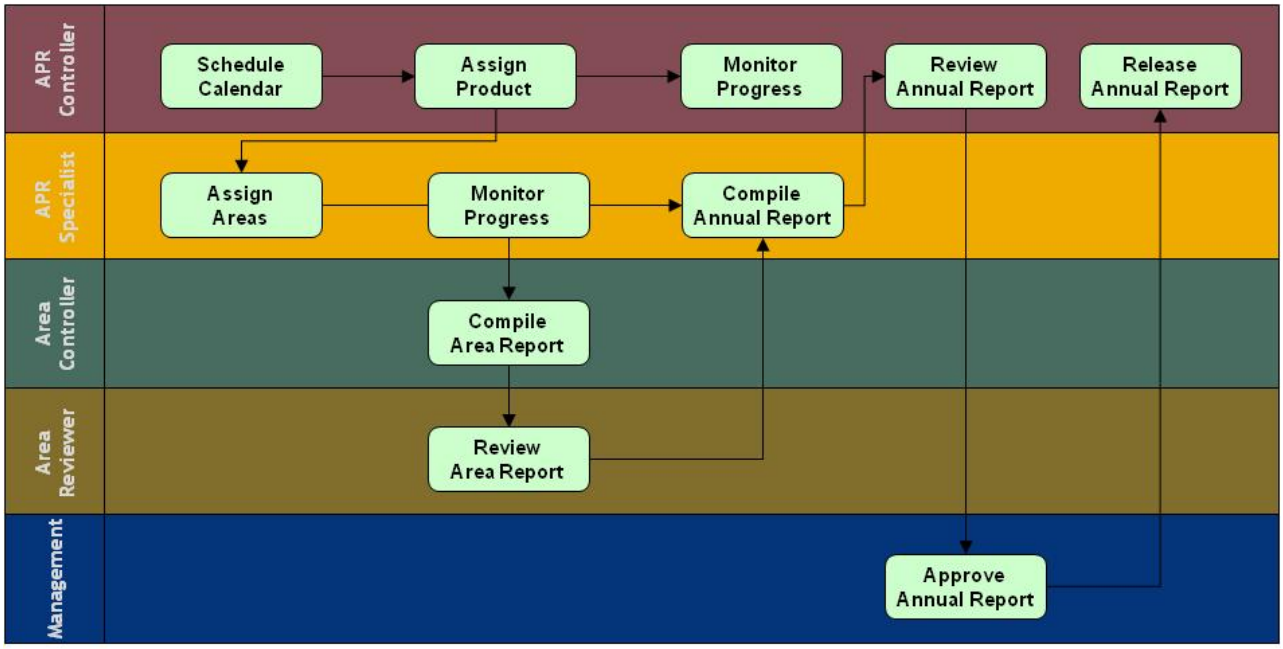
Liladhar Bagad is an Enterprise Architect, currently working at Intelligroup. He has worked with many Fortune 500 customers in successful implementations and supporting their key business processes using the state of the art technology. He is an active member of Enterprise Services Community and holds a proven thought leadership in BPM and SOA.

Table of Contents

Introduction to APR Process

Annual product review (APR) is required to be performed for each product produced for the commercial market to evaluate data, trends and to identify any preventative or corrective action that would lead to product quality improvements and report them to management. Given the regulations are clearly detailed for the Annual Product Review, the compilation and usage of the APR would be expected to widely well entrenched and established in the organization. But recent FDA investigation reports site deficiencies in the annual product review and there have been warning letter issues containing references to poor or inadequate APR.

Process Flow



APR provides very effective tools to look back on product performance to determine if changes are needed. An effective APR process would help to fine tune the product specification, ensure that changes made to the manufacturing or control processes are effective and/or ascertain further changes, establish the need for validation or revalidations, identify improvement opportunities, provides a high level view to understand the cumulative effects of several small changes and a possible negative effect and lastly, it provides a good tool for the management to take cognizance of concerns or areas that require corrective or preventive actions.

Like any good governance or quality management process, management commitment and belief in the effectiveness of an APR process and the benefits arising from an effective APR, the APR process would suffer. When FDA cites APR deficiencies, it assigns the responsibility to the management.

APR Solution – Our Vision for Composite Application

The Annual Product Review Community Definition Group (CDG) was formed by Intelligroup along with SAP ES Community. The purpose of this collaboration project was to validate the use cases with SAP Solution Management Group and select Customers, then detail out those Use Cases to see if relevant Enterprise Services exist, and define new ones that are needed. The initial goal of this project is to make this a semi automated solution built on the NetWeaver Platform. As the feeding processes mature and more data is available in electronic content, the process can be completely automated for the data collection part and would need only the observation and comments to be recorded.

The Annual Product Review composite application provides a flexible, scalable solution for the compilation of the pulling the data from the ERP system. Solution will help to schedule the review calendar for the products, compile the data pertaining to the areas mentioned below, if needed by several personnel in the organization and generate and publish the Annual Product review into a Document Repository. In addition, the system will support the capture of the Action or Recommendation arising from the review and track its progress and capture the status into the next APR. The solution will help to combine information for the standard APR

report as requested by FDA in the areas of: Recommendations from prior APR report, Batches manufactured, Batches rejected, Batches reworked/reprocessed, Deviations, Out of Specification Results (OOS),Environmental monitoring data, Product Specification/Method Changes, Retain samples, Changes effected (Change Control),Analytical data, Validation review, Recalls, Customer Complaints and Returns, Adverse Drug events ,Inspections from any official inspectorate and New recommendations.

APRs can be organized in a variety of ways. Some firms assemble comprehensive and detailed APRs that can comprise several hundred pages each. Others collect only minimal data and include extensive summaries of data. Any of the approaches can meet the regulatory expectations / GMP requirements if the minimum information required is included.

Design approach enables the deployments of the solution in several ways thereby improving productivity as well as the ability to draw a larger resource pool in the compilations. Additional elements or areas that may emerge can be easily incorporated. Although the current design, envisages the use of the ERP system, the team recognizes that in the actual eco system organization may be using several system for the areas. Design approach looks to use the standard SAP functionalities or features thereby ensuring minimal development requirements, consistency with the SAP architecture, no additional skill sets to be learnt by the IT personnel and more importantly leverages the Audit Trail and electronic signatures. Usage and assignment of roles enhance the access and authorization levels.

Summary

Silent Features of the APR Composite

- This solution streamlines and optimizes the process of compiling the Annual Product Review (APR)
- It will support a mainly semi- automated process of compiling an Annual Product Review report and it's tracking and tracing throughout the compilation process from scheduling to publication of the approved APR.
- The target market is the Pharmaceutical and Biopharmaceutical companies using the SAP ERP system.
- The solution will be a composite based on NW Composition Environment CE 7.1, will use SAP BPM functionality from EhP1 and mainly consuming backend ERP service operations from Enhancement Package 3.

Business Value from APR Composite

- Automated and more efficient process.
- Reduces Cycle time for Annual Product Report Compilation.
- Full visibility of the process
- Integrated with Core ERP System
- Promotes governance
- Improved customer satisfaction.
- Promotes Regulatory Compliances

As this program is launched through SAP ES Community, we have created a workspace PCDG 76 Annual Product Review for this group. Interested participants can request to join this group based on their requirements. We look forward to your participation and active contribution towards making this effort a successful one for Life-Sciences companies.

Related Content

Please refer to the following content for further details. This will definitely help you to get ready for our next article in this series.

PCDG 76 Annual Product Review

Code of Federal Regulations 21 CFR 211.180 (e)

SAP NetWeaver BPM

APR SOP Sample I

APR SOP Sample II

For more information, visit the Business Process Expert homepage.

Disclaimer and Liability Notice

This document may discuss sample coding or other information that does not include SAP official interfaces and therefore is not supported by SAP. Changes made based on this information are not supported and can be overwritten during an upgrade.

SAP will not be held liable for any damages caused by using or misusing the information, code or methods suggested in this document, and anyone using these methods does so at his/her own risk.

SAP offers no guarantees and assumes no responsibility or liability of any type with respect to the content of this technical article or code sample, including any liability resulting from incompatibility between the content within this document and the materials and services offered by SAP. You agree that you will not hold, or seek to hold, SAP responsible or liable with respect to the content of this document.