Agaram TECHNOLOGIES

WHITE PAPER

LIMS for Government Regulatory Labs

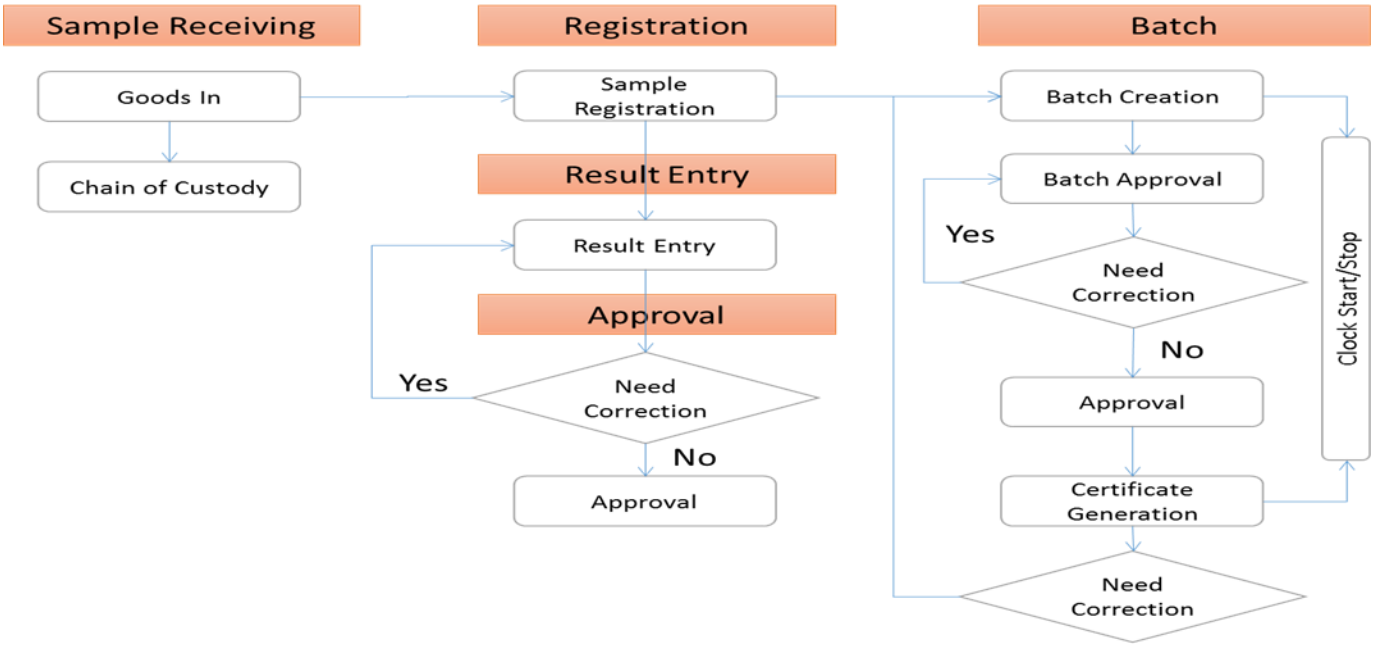
GOVERNMENT REGULATORY LABS

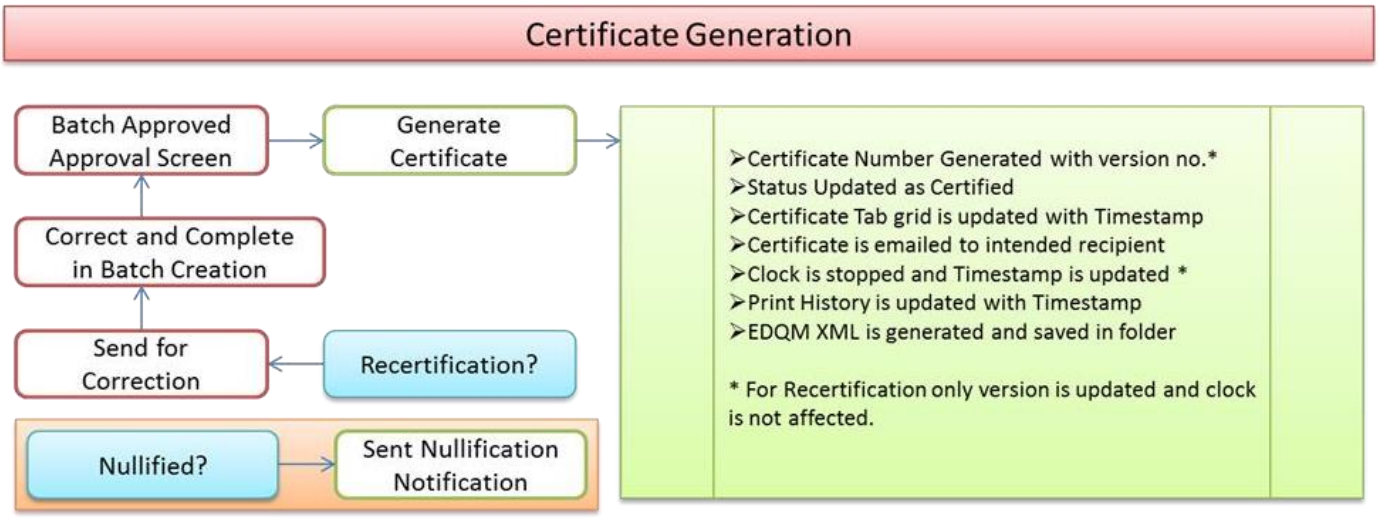
Government regulatory labs like the official medicines control labs perform control testing of various biological substances like vaccine, blood products and immunological substances. These labs perform testing on almost every batch to be released in European market. The process of product batch release involves the analysis of finished product batch along with raw materials and ingredients used in the process of manufacturing and preparation of such products. These batches are released or put on hold against a specification that is acceptable in the country or region of intended sale of the batch. The control testing lab releases the final certificate as Pass/Fail based on outcome of testing conducted.

CHALLENGES AND SOLUTION

Challenges	Solution
Product supervisor should know the product and ingredients to be verified	Study Plan allows defining product structure and test requirement for each product and product components
Specifications should be validated for release based on country / product specification	Study Plan also allows definition of multilevel specification based on Country/Dosage etc.
Manufacturer provided results to be available for comparison with ease	Manufacturer results can be added automatically on single click
High volume of samples to be managed with great accuracy and speed	Sample registration with easy copy techniques and excel import features allows fast registration of bulk samples
Review and validation of information for accuracy before release of certificate	Use of checklist at each stage with eSignatures allows proper verification of information required for controlled release
Batch creation & release of certificate in timely manner	Advanced batch creation tool available for easy creation of batch based on multiple components from different batches
Traceability of information and easy retrieval	QuaLIS data management makes sure all information required for testing process is properly correlated. Strong search capabilities are provided to easy traceability of required information like one-to-one (one component in one batch), one-to-many (one component in multiple batches)
Ensuring the activities are never missed and all activities are completed in time	Built-in alert and email reminders will ensure that the responsible user is promptly reminded of the pending task and duration of Completion. Escalation rules can ensure nothing is missed in the activity workflow

QUALIS LIMS WORKFLOW FOR CONTROL TESTING LABS





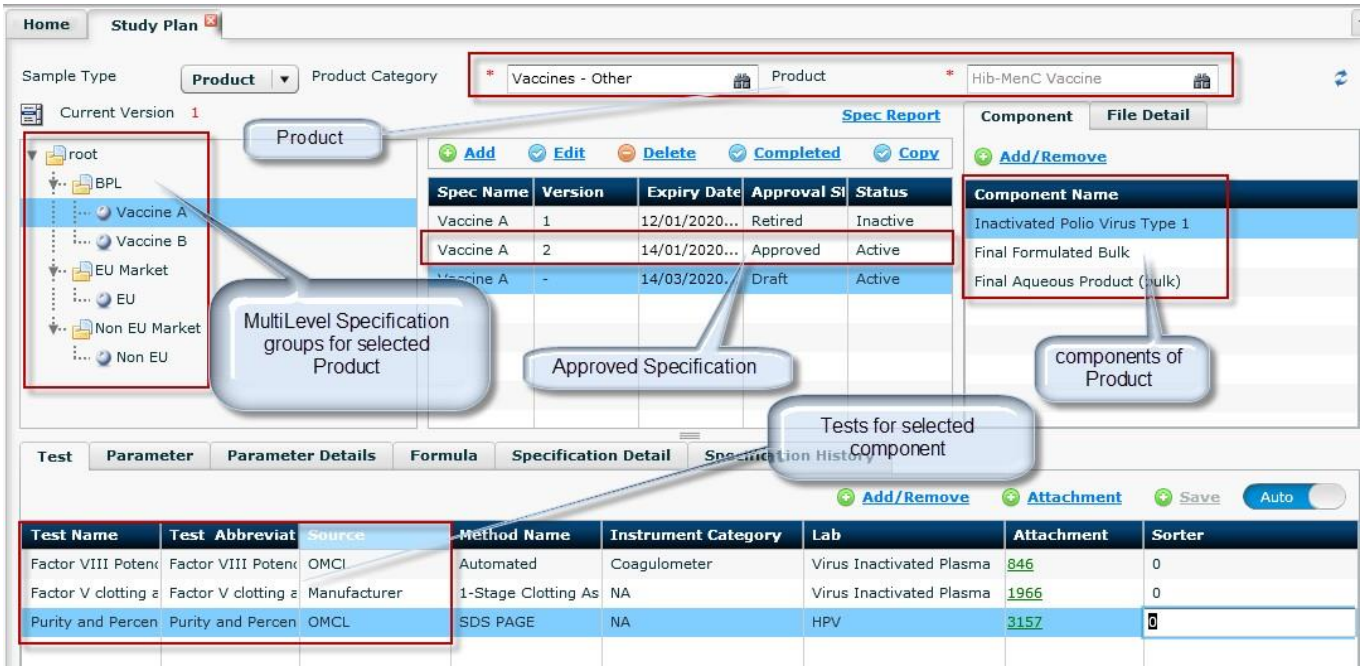
CONTACTS AND PRODUCT (MANUFACTURERS, MARKET AUTHORIZATION HOLDERS)

Different contacts such as manufacturers, MA holders, clients and suppliers can be managed and in turn can be associated with the samples analysed. Products and Components analysed can be managed and creation of product records can be controlled through review and approval before releasing to the end users.

TESTS & SPECIFICATIONS MANAGEMENT (STUDY PLAN)

Test masters with relevant attributes and switches can be maintained based on test category and sections that will handle tests. Tests can have one or multiple parameters. Parameters can be numeric, character, pre-defined values, attachments etc. Tests can be linked to instruments, rounding rules, analysis techniques which is in turn linked to personnel and their training records.

Specification templates can be created based on the nature how you would classify the product. These templates can be released in a controlled manner for creating specifications or study plans. The study plans are again version and release controlled. Each version of study plan can have multiple components and each component can have multiple tests.



SAMPLE REGISTRATION & TEST ORDERING

Samples (finished product, component, blood products) are registered with a unique Sample No with appropriate batch#, lot# and sent to respective testing sections like bacteriology, virology, blood products.

It is possible to perform complete specification based testing by selecting the appropriate profile and specification (EU/Non EU) for each sample. Testing priorities can also be set for samples.

RESULTS (CAPTURE FROM INSTRUMENTS USING ELECTRONIC LAB NOTEBOOK (ELN) & MIDDLEWARE)

Electronic lab notebook (ELN) was deployed to capture test method execution. This also involved interfacing of analytical instruments and clinical instruments. Analytical instruments were interfaced using the ELN which has a WYSIWYG template designing tool. Interfacer® a middleware for integrating clinical instruments was deployed to interface IVD instruments (HPV/HCV) which are used in blood products screening and testing.

APPROVAL

Qualis approval workflow steps can be configured to achieve multiple levels of approvals and actions to be performed on such approvals. First level of approval after results entry completion is done by a “Checker” who can check all the results, calculations, raw-data etc. The checker can mark samples and tests as “checked”. The checker can even recommend re-test/re-calculation to the next level. After checker the sample moved to a “Verifier” typically a section head who can verify all the data and if necessary can order for a re-test or re-calculation. The sample moves through the department head and QA where the final release/reject disposition is made.

BATCH CREATION AND RELEASE

Creation of Batch and marking completion. Review and Approval of Batch with correction flow. Certificate Generation and correction flow. Clock Monitoring with manual Start/Stop options.

Batch creation involves defining the Batch information as per Manufacturer Protocol and associating batch components. Batch can be copied from previous records if there is small variation in it and modified for the required changes.

CERTIFICATES

Certificated review and approval before dispatch is managed in certificate screen. The certificate dispatch can be automated so that once the final approval is marked, the certificate is sent by email to the related recipient. Appropriate template is automatically selected based on the decision like Pass/Fail/Withdrawal. KIP Status is displayed to ensure the certificate is sent out in timely manner. Correction flow with history ensures any changes made to the certificate release are controlled and history is maintained.

EMAIL ALERTS

Configurable Email alert module ensures no activity is ignored unnoticed even if the user is not on desk. An email alert with buffer time notification can be configured for important activities with proper message body and subject line. Dynamic values like Sample Number, Batch ID for the event can be embedded in the alert message.

COMPLIANCE AND QA REQUIREMENTS

Configurable workflows for approval

Each organization has its own QA practice for approval flow. This also varies based on type of product or product stage. Configurable approval workflow ensures such needs are achieved based on sample types.

E-Signature

E-Signature facility in line with 21 CFR Part 11 & Eudralex Annex 11.Unique combination of user id and password to approve records. Date &Time Stamp from system is recorded at the time of eSignature along with user details. Changes made to the original data are versioned and audit trailed.

Audit Trail

Audit trail is maintained in line with 21 CFR Part 11. Any changes to the original data are audit trailed either silent or active (with eSignature) as per the configuration. Audit trail can be exported or printed in user readable format. Every record transaction is time stamped with logged in user details.

Security

Software is designed to be used with complete user security as per 21 CFR Part 11. Unique user id and password is required to access the application. Access control is provided to the logged in user based on configuration set by administrator user typically based on role.

BENEFITS OF THE SYSTEM

- The system brings in full traceability including chain-of-custody of sample right from goods inward to release of certificate
- Better co-ordination between multiple departments
- Better control of study plan and specifications
- Collaborative approach reduces the time spent in follow-ups and meetings to get things done
- Batch creation (multiple components tested at different time-points) and release helps in quick release of batches.
- Easy to monitor and follow key performance indicators
- Increases throughput of the lab
- Avoids duplication of work
- Alerts help in keeping up with performance metrics
- GLP, 21 CFR Part 11, Eudralex Annex 11 recommendations can be handled seamless
- Easy integration with EDQM for submission of result outcome of batches

Agaram Technologies (HQ)

Priyan plaza 76 Nelson Road
Aminjikarai
Chennai 600 029,India
T: +91 44 42082005
E: info@agaramtech.com

Agaram Technologies(KOREA)

941 Hogye-Geumjeong SK V1 Center
42, LS-ro, Dongan-gu,Anyang-si,
Gyeonggi-do 14118,KOREA
T: +82 31 429 8958
E: info@agaramtech.com

Agaram Technologies(USA)

20130, Lakeview Center Plaza
Suite 400, Ashburn
VA 20147, U.S.A
T: +1-703-297-8591
E: info@agaramtech.com

info@agaramtech.com

www.agaramtech.com