

# Regulated Vendor Management System

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## ABSTRACT

As providers of human ocular tissue for transplant, we will enter into agreements with organizations that perform or support a manufacturing step on our behalf. For example, an eye bank may send a cornea determined eligible for transplant to another eye bank for specialized processing (e.g., laser-enabled keratoplasty). FDA provides guidance on the responsibility of the customer (the source eye bank in this case) in ensuring the vendor’s (the processor in this case) regulatory compliance. A modern eye bank is likely to have many vendors performing and supporting manufacturing steps like: serology testing, record storage, media storage, tissue processing, and perhaps terminal sterilization. The purpose of this review is to outline one eye bank’s system for onboarding, maintaining, and addressing non-conformances with such *Regulated Vendors*.

## CLASSIFICATION AND SOFTWARE

A Regulated Vendor is defined in policy as an “Organization who performs a service for the eye bank that relates to FDA HCT/P requirements or EBAA medical standards.” As a foundation of this system for vendor management, regulated vendors are split into three categories according to the risk-level of the service they provide (Figure 1). Level 1 vendors perform a manufacturing step on behalf of the eye bank and include serology testing facilities, tissue

processors, and terminal sterilization facilities. Level 2 vendors perform a function that supports a manufacturing step for the eye bank and include media storage facilities, equipment maintenance vendors, and external sterilization services of supplies. Level 3 vendors perform a step not directly related to a manufacturing step but with specific requirements and include record storage and destruction services, among others.

The “Vendors” module of Q-Pulse (Ideagen Plc.) software is a critical tool in the eye bank’s regulated vendor management system. Figure 2 shows a *Vendor Detail* page for a level 1 regulated vendor, VRL Laboratories, which illustrates the capability of the Q-Pulse vendor module. At the top of the page a category field displays “Donor Testing” which corresponds to a table in the policy for regulated vendors. This policy contains a table detailing how the initial qualifier will perform initial qualification and the account manager will perform ongoing qualification (Figure 3). In addition, the vendor detail page permits assigning an account manager and automatically generating email reminders to re-qualify the vendor. Finally, the vendor page serves as a document repository for electronic storage of initial/ongoing qualification forms, registration forms, and regulatory certifications.

Vendor Level:	Level 1	Level 2	Level 3
Function:	Perform manufacturing step	Support manufacturing step	Not related to a manufacturing step
Initial Qualifying Party:	Chief Quality Officer	Quality Program Manager/Department Head	Quality Program Manager/Department Head
Ongoing Qualifying Party:	Account Manager	Knowledgeable Employee	No renewal

Figure 1: Classification, function, and responsible party for regulated vendors.

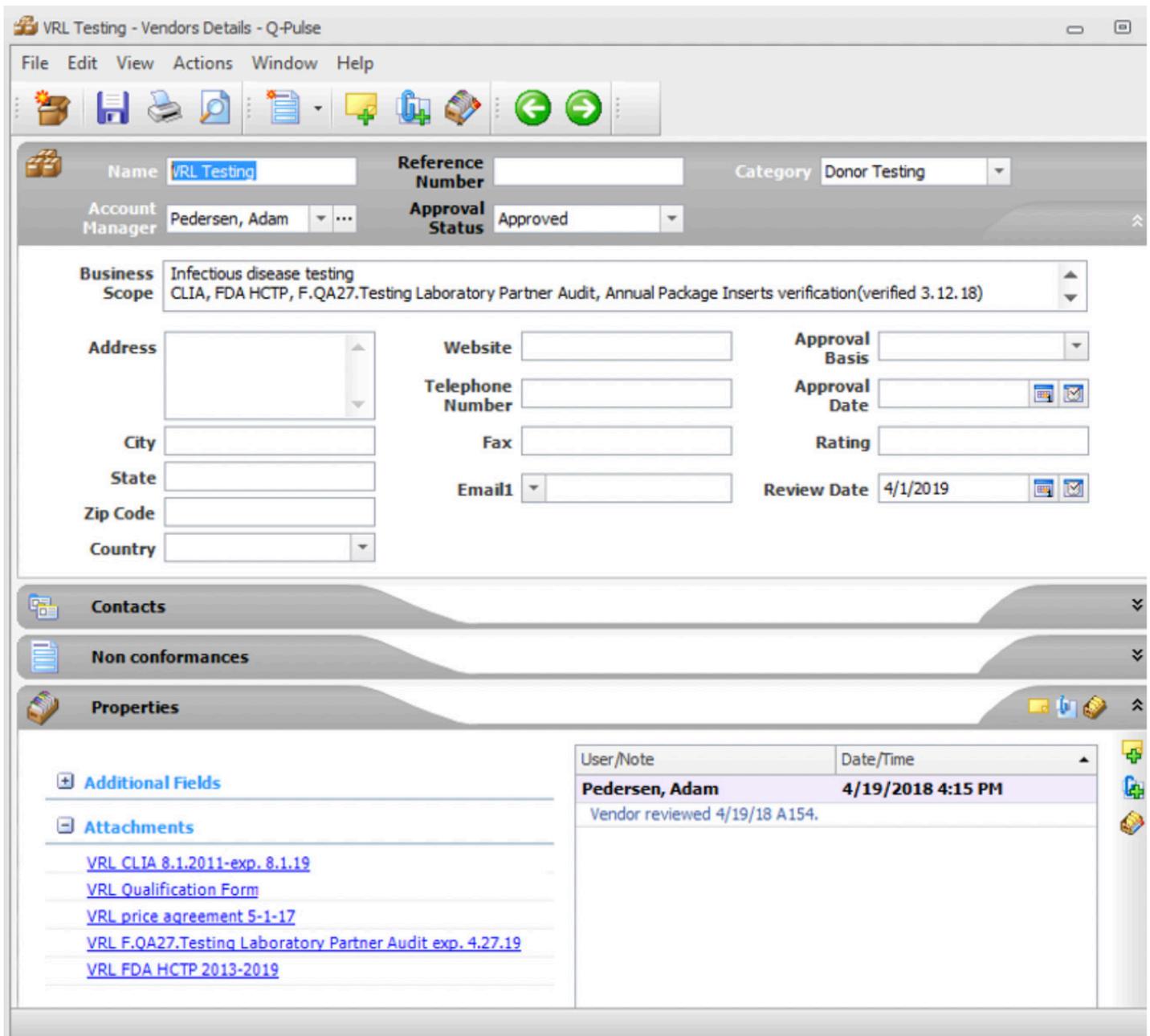


Figure 2: Vendor detail page in Q-Pulse

### INITIAL VENDOR QUALIFICATION

*FDA 1271.150(c)(1): Before entering into a contract, agreement, or other arrangement with another establishment to perform any step in manufacture for you, you must ensure that the establishment complies with applicable CGTP requirements.*

Initial qualification of a regulated vendor is done by completing a *Vendor Qualification Form*. The responsible party

enters basic information about the vendor and the service it provides and is asked to indicate the following: non-disclosure agreement and contract/quality agreement considerations, the name of the account manager, the sub category of vendor (donor testing, tissue irradiation, record storage, etc.), and for which location the vendor will provide service. Next, following the table in Figure 3, the qualifier obtains, completes, and uploads into Q-Pulse all the items required in the “Initial Qualification” column. For ex-

Service	Initial Qualification	Ongoing Qualification
Donor Screening	<ul style="list-style-type: none"> <li>HCT/P FDA Registration for screening cornea and sclera</li> <li>AATB accreditation</li> <li>Review SOP related to screening</li> <li>CMS certification</li> <li>AOPO accreditation</li> <li>Review SOP related to screening</li> </ul>	Annual: <ul style="list-style-type: none"> <li>Registrations/Certifications/Accreditations tracked.</li> <li>Confirm no changes to relevant SOPs, or changes were reviewed, or changes not relevant to service provided.</li> </ul>
Donor Testing	<ul style="list-style-type: none"> <li>HCT/P FDA registration for testing for cornea and sclera</li> <li>CLIA certification for syphilis serology, general immunology and ABO Group &amp; Rh Group</li> <li>Complete F.QA27.Testing Laboratory Partner Audit</li> <li>Verify use of approved test kits</li> </ul>	Annual: <ul style="list-style-type: none"> <li>Registrations/Certifications tracked</li> <li>Verify use of approved test kits</li> </ul> Biennial: <ul style="list-style-type: none"> <li>Desk audit with F.QA27.Testing Laboratory Partner Audit, or audit results from approved 3<sup>rd</sup> party auditor.</li> </ul>
Microbiology	<ul style="list-style-type: none"> <li>CLIA certification for bacteriology and mycology</li> <li>HCT/P FDA registration for processing sclera, cornea, and pericardium tissue</li> <li>Complete F.QA27.Testing Laboratory Partner Audit</li> </ul>	Annual: <ul style="list-style-type: none"> <li>Registrations/Certifications tracked</li> <li>Verify use of approved test kits</li> </ul> Biennial: <ul style="list-style-type: none"> <li>Desk audit with F.QA27.Testing Laboratory Partner Audit, or audit results from approved 3<sup>rd</sup> party auditor.</li> </ul>
Ocular Tissue Processing	Open-Container Tissue Processing (e.g., IK, EK) <ul style="list-style-type: none"> <li>EBAA Accreditation for processing, storage, tissue evaluation, distribution</li> <li>HCT/P FDA registration for processing cornea and sclera</li> <li>Complete F.QA25.OCP Partner Audit</li> </ul>	Annual: <ul style="list-style-type: none"> <li>Registrations/Accreditations tracked,</li> </ul> Biennial: <ul style="list-style-type: none"> <li>Desk audit with F.QA25.OCP Partner Audit, or audit results from approved 3<sup>rd</sup> party auditor.</li> </ul>
Tissue Irradiation	<ul style="list-style-type: none"> <li>HCT/P FDA registration for processing cornea, sclera, and pericardium</li> <li>FDA CDRH registration</li> <li>Complete form F.QA26.Irradiation Partner Audit.</li> </ul>	Annual: <ul style="list-style-type: none"> <li>Registrations tracked.</li> </ul> Biennial: <ul style="list-style-type: none"> <li>Desk audit with F.QA26.Irradiation Partner Audit, or audit results from approved 3<sup>rd</sup> party auditor.</li> </ul>

Figure 3: Regulated vendor sub-categories and requirements for initial and ongoing qualification.

ample, to qualify an *Ocular Tissue Processing* facility, the qualifier will obtain and upload the vendor’s relevant EBAA Accreditation, HCT/P FDA registration for processing cornea/sclera and complete the *Open Container Processing Partner Audit* form.

Partner audit forms are specific to the sub-category of regulated vendors. Some examples are: *Testing Laboratory Partner Audit Form*, *Irradiation Partner Audit Form*. The partner audit forms are specific to the sub-category of vendor and contain questions about:

- Major changes since the last audit (e.g., change in key personal, outsourcing of services, change in services provided)
- Agreement to contact LVG prior to implementation of major changes
- Acceptable outcomes of recent regulatory agency inspections
- SOP in place for relevant processes
- Records management
- Training program and competency review
- Quality program

After the partner audit is complete and relevant certificates/registrations are uploaded into Q-Pulse, the initial qualifier may approve the regulated vendor for performing or supporting a manufacturing step.

### ONGOING VENDOR QUALIFICATION

Ongoing qualification is completed by an account manager (level 1 vendors) or by a knowledgeable employee (level 2 vendors) on a schedule defined in policy. Steps to complete the ongoing qualification are defined in policy and shown in Figure 3.

### VENDOR NONCONFORMANCES

*FDA 1271.150(c)(1): If, during the course of this contract, agreement, or other arrangement, you become aware of information suggesting that the establishment may no longer be in compliance with such requirements, you must take reasonable steps to ensure the establishment complies with those requirements.*

On occasion, the eye bank is made aware of nonconformance related to performance of a manufacturing step on its behalf. To address the nonconformance and take the “reasonable steps to ensure the establishment complies with those requirements,” the eye bank sends a *Supplier Corrective Action Request (SCAR)* to the vendor. The SCAR has 4 sections:

1. Description of Nonconformance (completed by the eye bank)
2. Corrective Action Plan (completed by vendor)
3. Evidence of completion of Corrective Action Plan (completed by vendor)
4. Effectiveness Check (completed by eye bank)

In the case of an outstanding SCAR, the eye bank will evaluate whether to suspend activities performed by that vendor until satisfactory completion of the SCAR.

### **CONCLUSION**

The system for managing regulated vendors is defined in policy and the tightest controls are reserved for the vendors with the highest risk. The system is executed through the completion of forms for initial qualification, partner audit, and supplier corrective action request. The entire

framework is organized electronically using Q-Pulse’s “Vendors” module where account managers are assigned, documents are stored, and reminders are automatically generated for ongoing qualifications. FDA’s guidance on the management of regulated vendors makes it clear that the eye bank is responsible for ensuring that its vendors comply with CGTP.

### **REFERENCES**

Human Cells, Tissues, and Cellular and Tissue Based Products, 21 CFR Part 1271.150(e)(1).