The world's true measure of color
HunterLab

IQ/OQ/PQ for Color Measurement Instrumentation

Ensuring performance and meeting regulatory requirements in the pharmaceutical industry

Speaker

Ken Phillips

Market Development Manager
Hunter Associates Laboratories

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REVIEW:
What Color is your Drug Solution?

Paul Barnes
Product Manager
HunterLab

Webinar: What Color is Your Drug Solution? Quantitative vs. Qualitative Color Measurement

Sponsored by: HunterLab

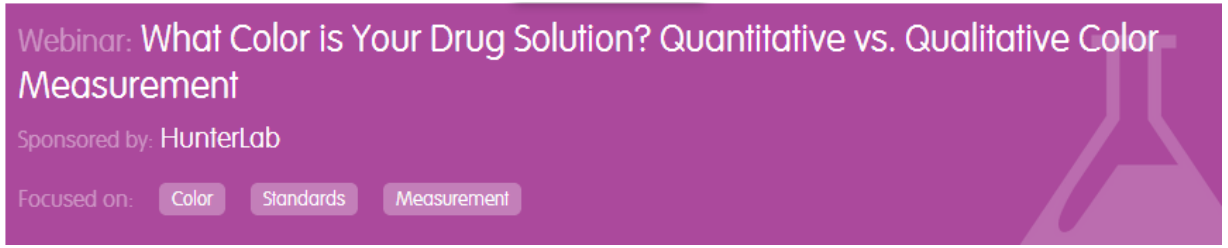
Focused on: Color | Standards | Measurement

An eye toward setting pharmaceutical color specifications in the future

Key Learning Objectives

- What is colorimetry? HINT: It is not UV/VIS spectrophotometry
- Uses and benefits of color measurement - from discovery to GMP
- Implementing objective analytical color measurement methods – moving beyond visual
- Conformance to global standards – what you need to know

REVIEW:
What Color is your Drug Solution?



An eye toward setting pharmaceutical color specifications in the future

Video
www.business-review-webinars.com/videos/t7H2NPWk/

PDF Slide Deck
www.business-review-webinars.com/webinarslides/Hunterlab_Webinar_04-06-2014.pdf

The world's true measure of color
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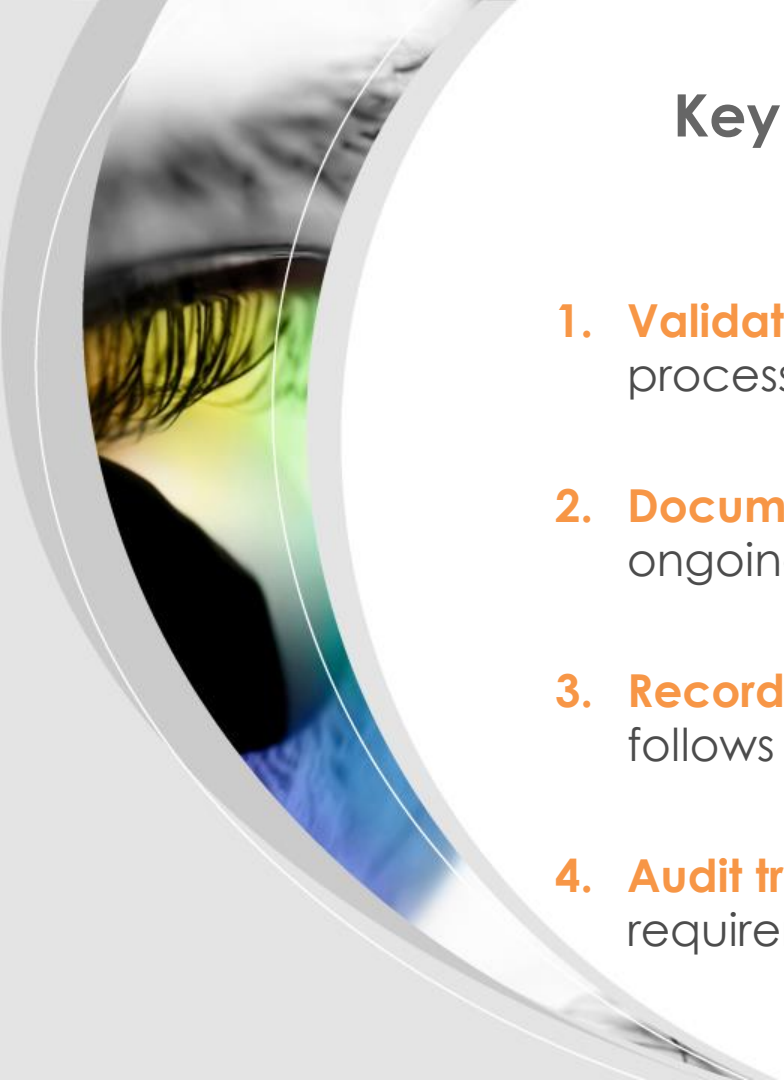
IQ/OQ/PQ for Color Measurement Instrumentation

Ensuring performance and meeting regulatory requirements in the pharmaceutical industry



Key Learning Objectives

1. **Validation and Qualification** - Understanding the ‘Q’ process

2. **Documented testing** - confirming proper initial and ongoing Installation, Operation, and Performance

3. **Recording instrument history** - ensuring your instrument follows GLP and GMP guidelines

4. **Audit trails** – meeting internal and external validation requirements

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'The 'Qs'

Qualification Protocols

Validation

- As a requirement for Good Manufacturing Practices and other regulatory requirements, the goal of validation is to:

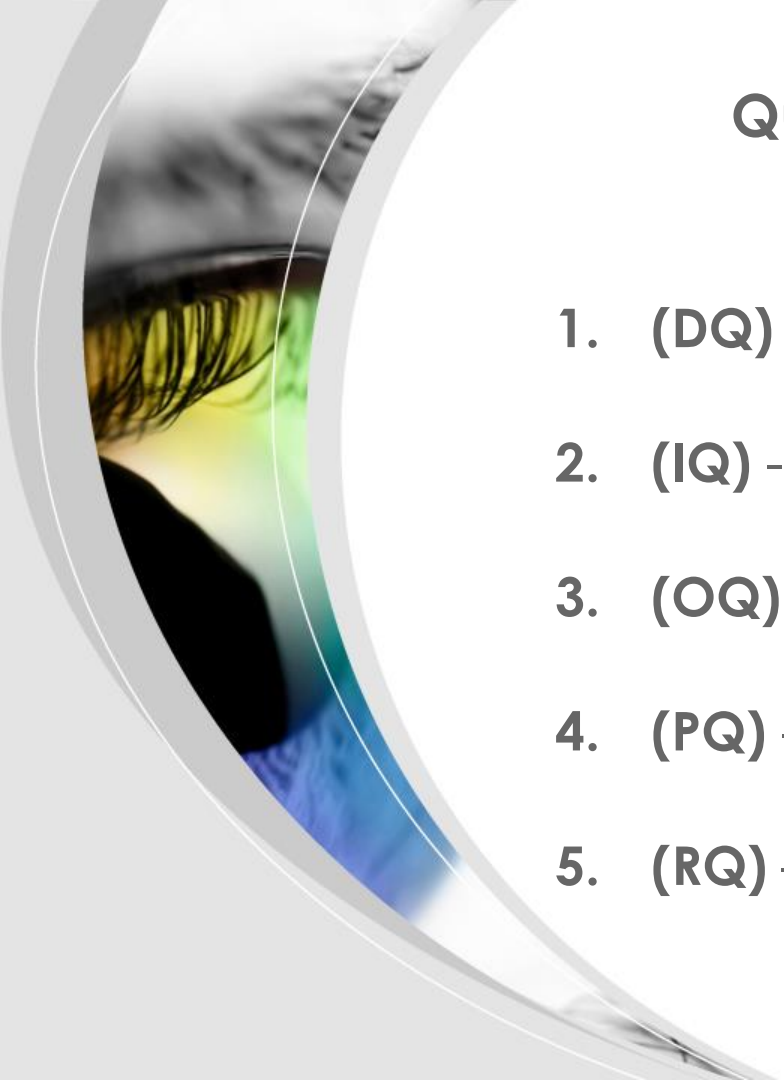
"Establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes"

Food and Drug Administration (FDA)

Validation vs. Qualification

- **Validation** is a quantitative approach that proves quality, functionality, and performance of a manufacturing process

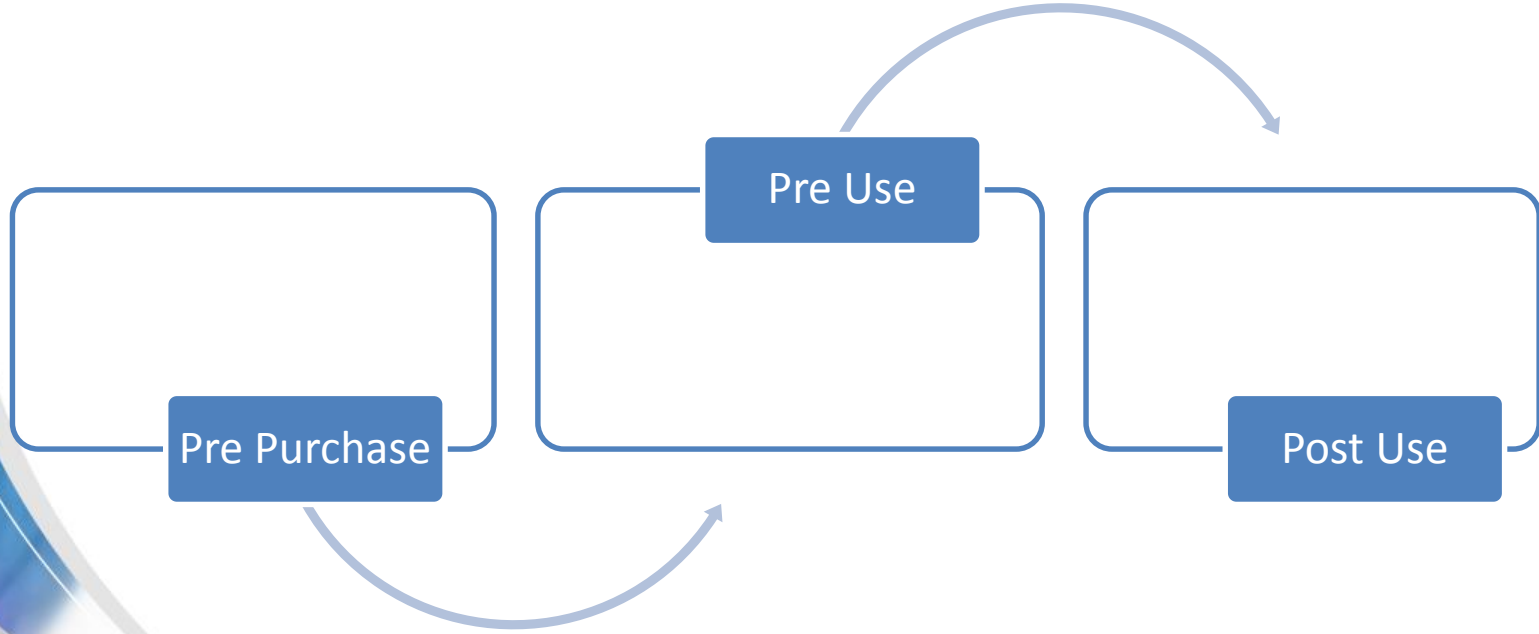
- **Qualification** is applied to individual pieces of equipment as well as the manufacturing process as a whole



Qualification Phases

1. **(DQ)** - Design Qualification
2. **(IQ)** - Installation Qualification
3. **(OQ)** - Operational Qualification
4. **(PQ)** - Performance Qualification
5. **(RQ)** – Requalification

‘Q’ Validation Process



‘Q’ Validation Process

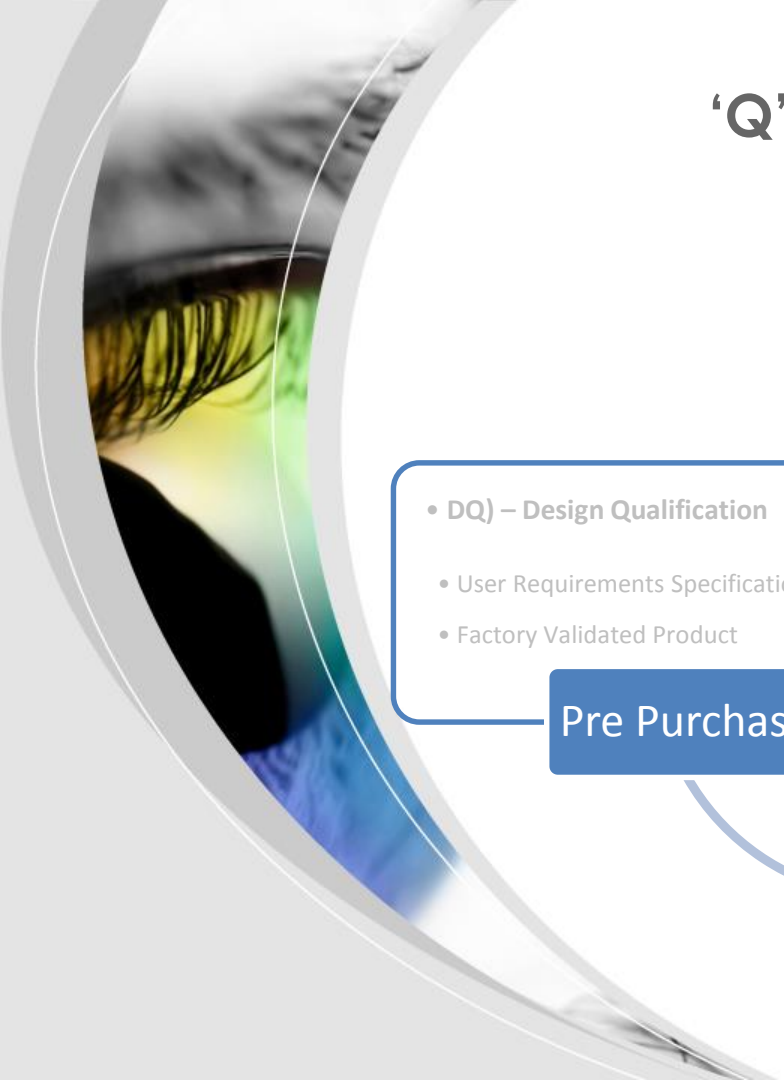
- **(DQ) – Design Qualification**
  - User Requirements Specification
  - Factory Validated Product

Pre Purchase

Pre Use

Post Use

‘Q’ Validation Process



Pre Purchase

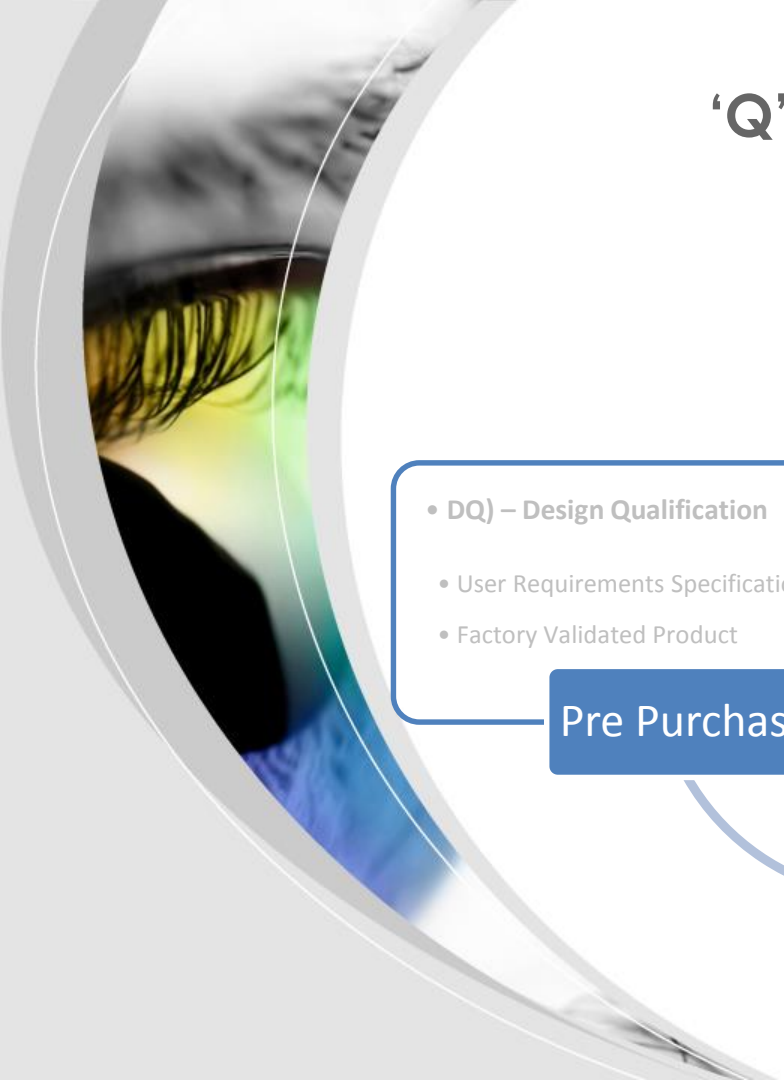
- DQ) – Design Qualification
  - User Requirements Specification
  - Factory Validated Product

Pre Use

- **(IQ)** – Installation Qualification
- **(OQ)** – Operational Qualification
- **(PQ)** – Performance Qualification

Post Use

‘Q’ Validation Process



Pre Purchase

- DQ) – Design Qualification
  - User Requirements Specification
  - Factory Validated Product

Pre Use

- (IQ) Installation Qualification
- (OQ) – Operational Qualification
- (PQ) – Performance Qualification

Post Use

- **(RQ) - Requalification**
  - **(OQ)** – Operational Qualification
  - **(PQ)** - Performance Qualification

‘Q’ Validation Process

Pre Purchase

- **(DQ) – Design Qualification**
  - User Requirements Specification
  - Factory Validated Product

Pre Use

- **(IQ)** Installation Qualification
- **(OQ)** – Operational Qualification
- **(PQ)** – Performance Qualification

Post Use

- **(RQ) - Requalification**
  - **(OQ)** – Operational Qualification
  - **(PQ)** - Performance Qualification

‘Q’ Validation Process

Pre Purchase

- **(DQ) – Design Qualification**
- User Requirements Specification
- Factory Validated Product

Pre Use

- **(IQ)** Installation Qualification
- **(OQ)** – Operational Qualification
- **(PQ)** – Performance Qualification

Post Use

- **(RQ) - Requalification**
- **(OQ)** – Operational Qualification
- **(PQ)** - Performance Qualification

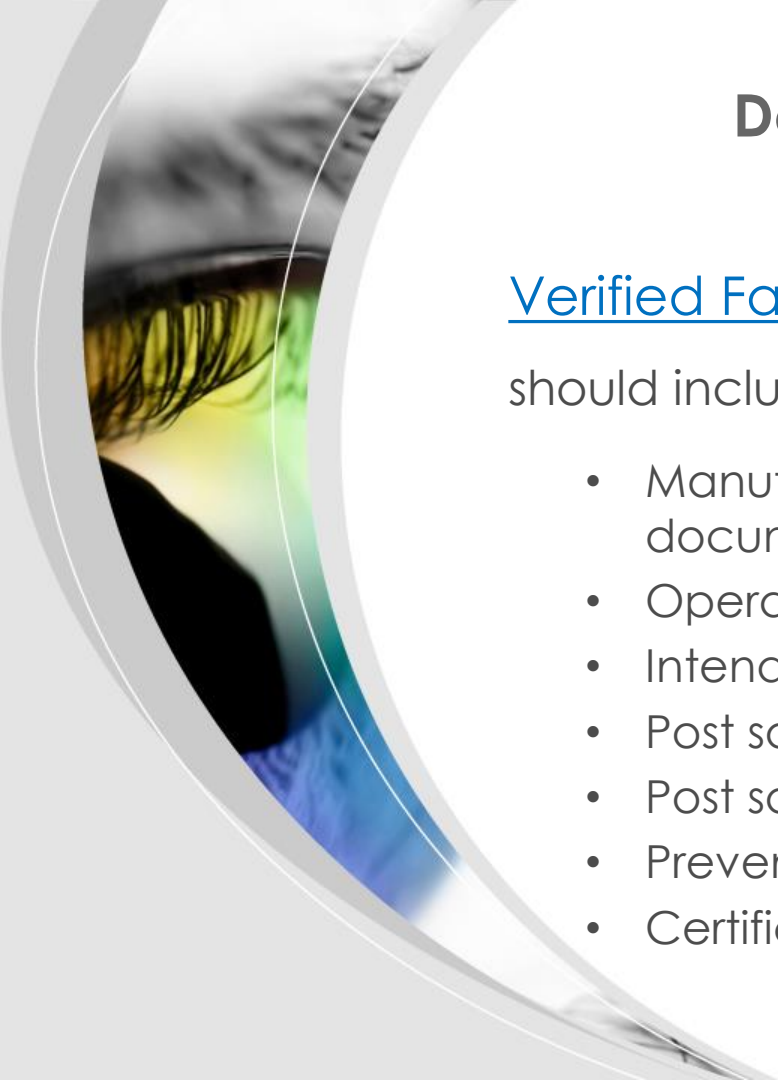
Design Qualification

(URS) User Requirements Specification

Describes the requirements the equipment must meet to be successful:

- Description and analysis of the problem
- Intended use of equipment and environment
- Preliminary selection of functional and performance specifications
- Final selection of supplier and equipment
- Development and documentation of specifications

Design Qualification

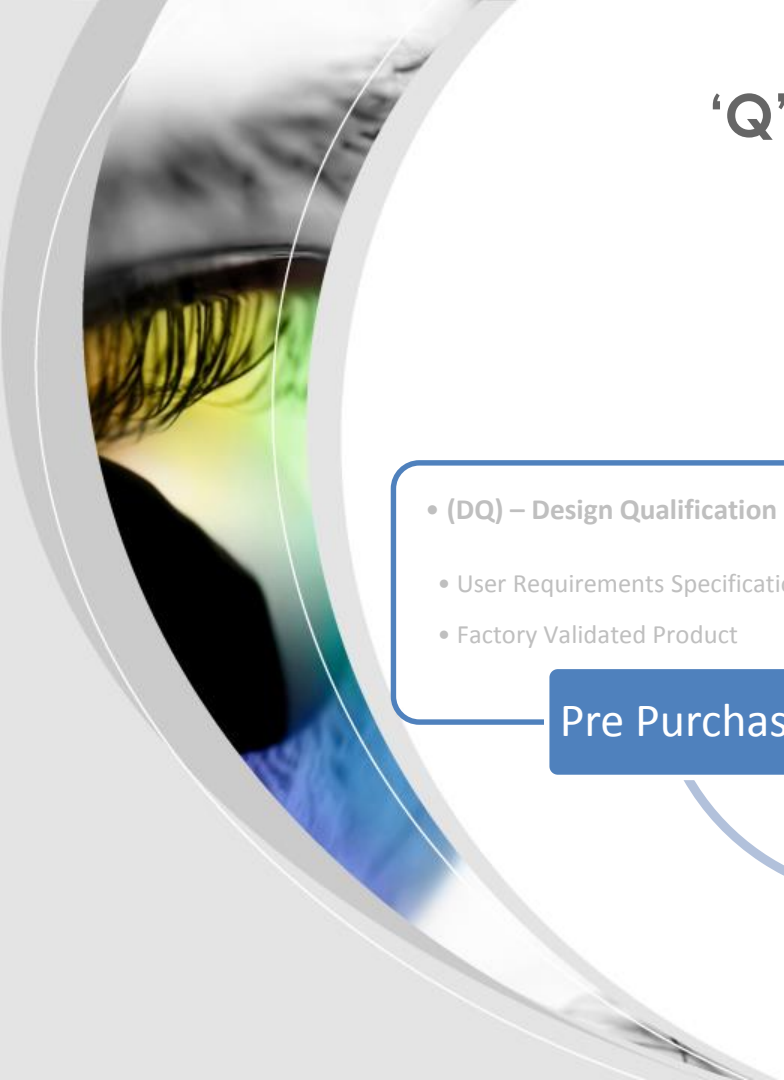


Verified Factory Product

should include (but not limited to):

- Manufacturing Test and Validation procedures with documentation
- Operational Features
- Intended Use
- Post sale Training support
- Post sale Installation support
- Preventive maintenance programs
- Certifications (ISO:9001…)

‘Q’ Validation Process



Pre Purchase

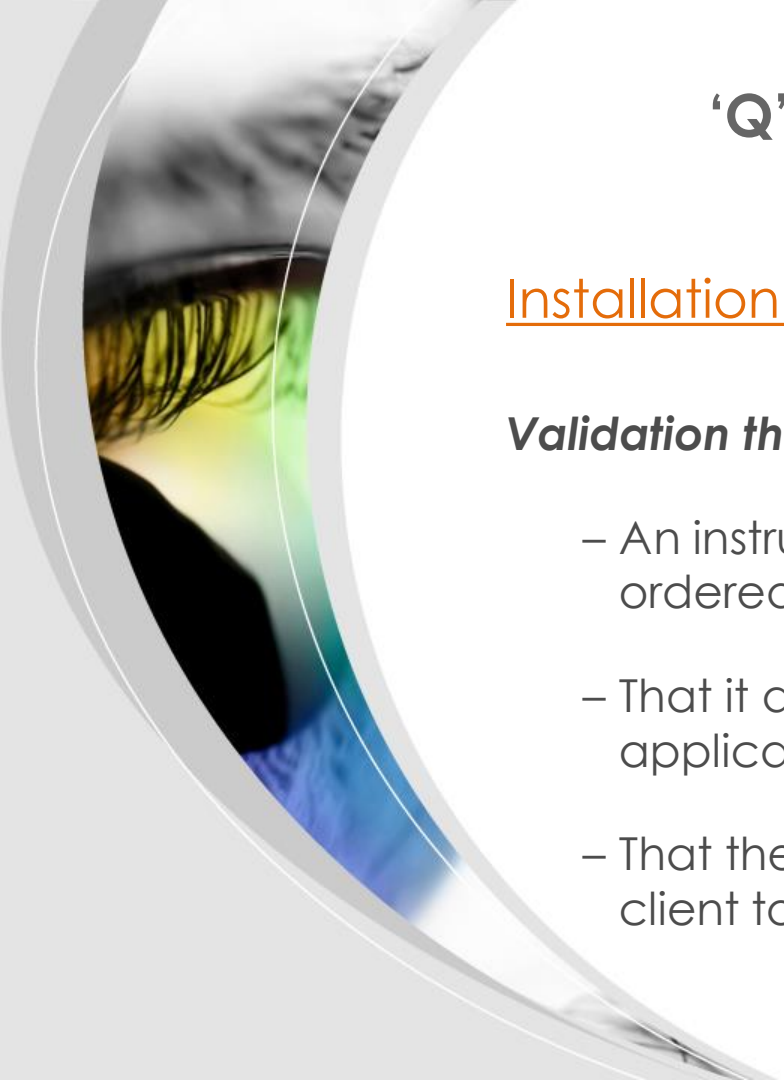
- **(DQ) – Design Qualification**
  - User Requirements Specification
  - Factory Validated Product

Pre Use

- **(IQ)** – Installation Qualification
- **(OQ)** – Operational Qualification
- **(PQ)** – Performance Qualification

Post Use

- **(RQ) - Requalification**
  - **(OQ)** – Operational Qualification
  - **(PQ)** - Performance Qualification



‘Q’ Validation Process

Installation Qualification

Validation that:

- An instrument and its components have been supplied as ordered and properly installed
- That it delivers to the requirements for a specific application
- That the supplier delivers sufficient documentation to the client to enable future maintenance and performance

‘Q’ Validation Process

Operational Qualification

Performed after the IQ phase to validate:

- The equipment is able to perform the task for which it is intended
- Demonstrates that the instrument will function according to its operational specifications

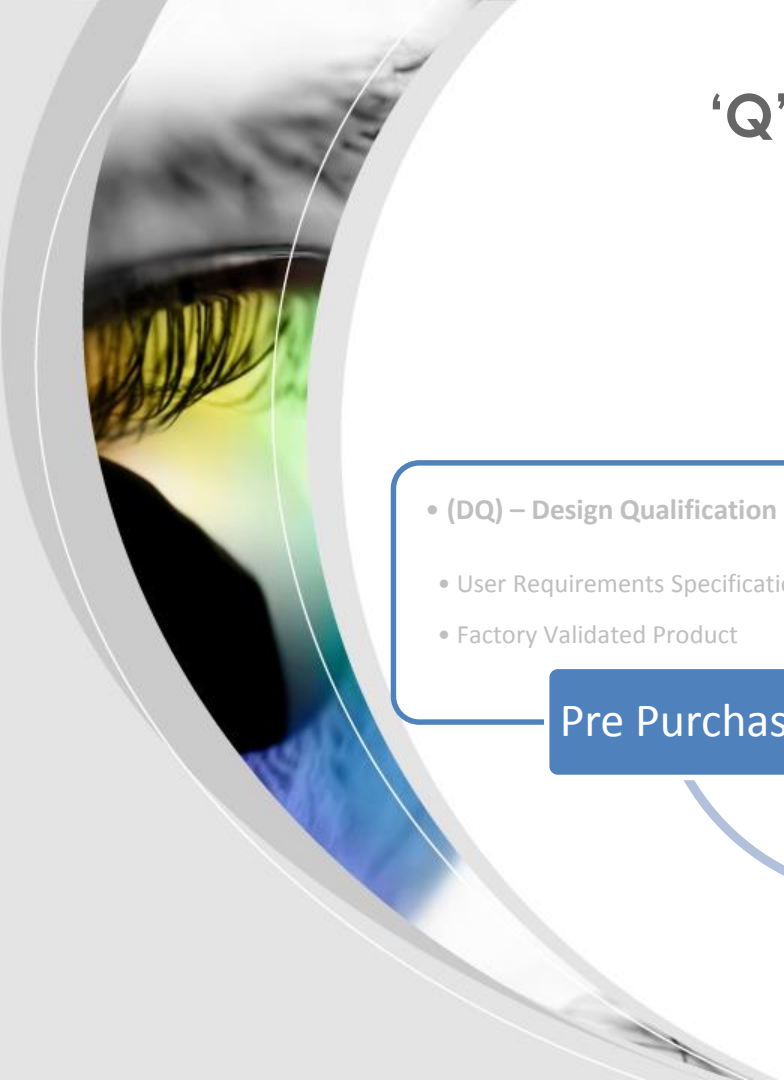
‘Q’ Validation Process

Performance Qualification

Performed after successful execution and completion of the **IQ** and **OQ** phases to validate:

- Delivery of performance to the specifications outlined in the URS
- Conformance to the requirements specified in cGMP’s, health and safety rules and other guidance documents

‘Q’ Validation Process



- **(DQ) – Design Qualification**
  - User Requirements Specification
  - Factory Validated Product

Pre Purchase

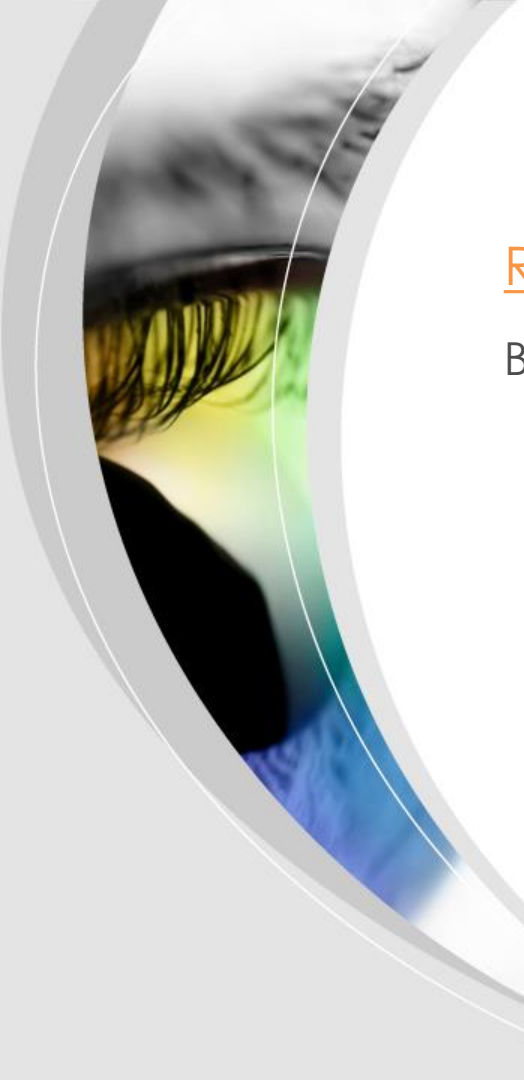
Pre Use

- **(IQ)** – Installation Qualification
- **(OQ)** – Operational Qualification
- **(PQ)** – Performance Qualification

- **(RQ) - Requalification**
  - **(OQ)** – Operational Qualification
  - **(PQ)** - Performance Qualification

Post Use

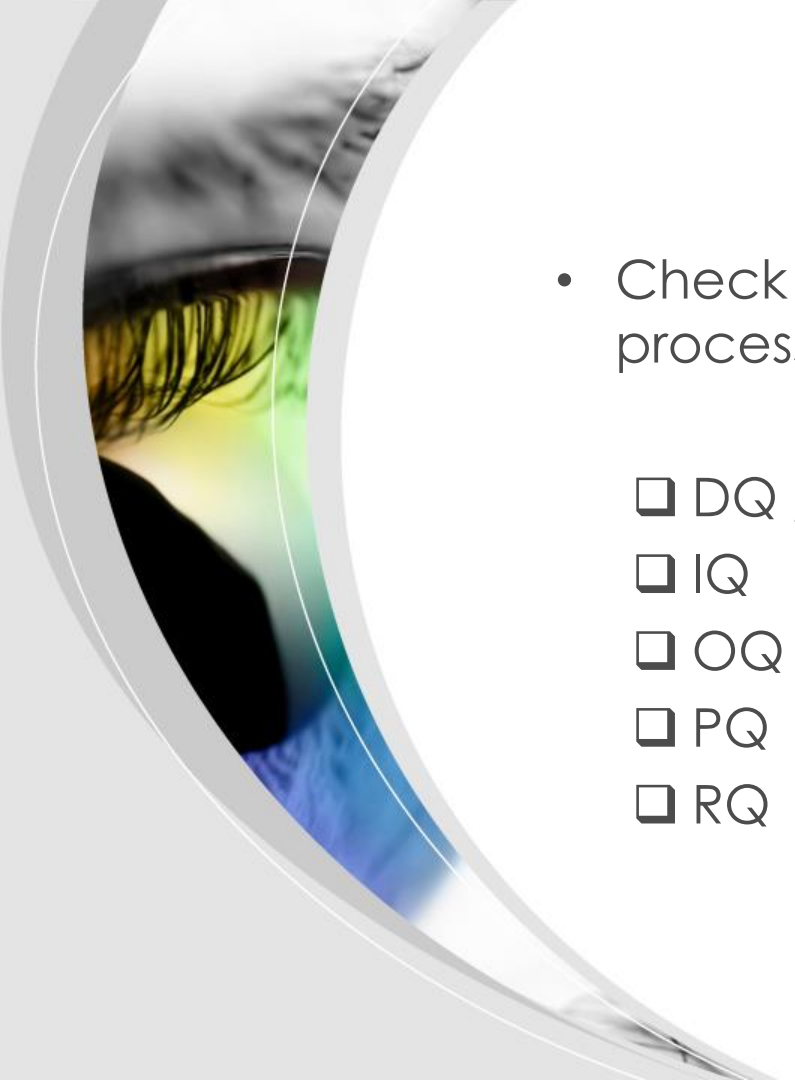
‘Q’ Validation Process



Requalification

Both ***USER and SUPPLIER responsibilities*** working in together to:

- Describe and document any maintenance required on the equipment
- Include routine servicing and any repairs necessary
- Detail any maintenance contracts together with a list of authorized service agent
- Include the routine cleaning of the equipment
- Include annual factory maintenance and recertification requirements
- Include requalification schedule



POLL QUESTION

- Check the boxes for each formal qualification process you currently follow:

  - ❑ DQ / USR
  - ❑ IQ
  - ❑ OQ
  - ❑ PQ
  - ❑ RQ

The world's true measure of color

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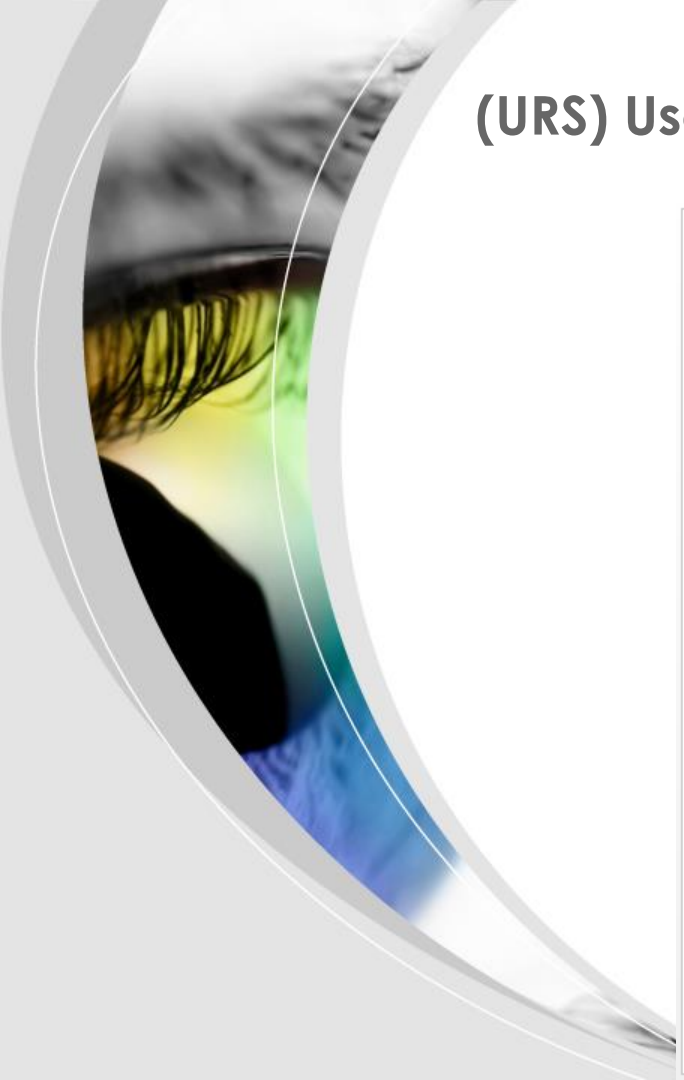
(URS) User Requirements Specification

The Key to Successful IQ/OQ/PQ/RQ

(URS) User Requirements Specifications

- User Requirements Specifications are the most important, yet most often overlooked, in developing and implementing validation and qualification processes
- URS provides understanding of:
  - business and process needs
  - Key Stakeholders affected
  - Instrument Design and Functional Requirements
  - Key support documentation and references
- Once the URS is defined and agreed to by key stakeholders, then the successful purchase and execution of the **'Q'** phases can be executed
- Successful IQ/OQ/PQ/RQ is dependent on clear, concise and testable requirements

(URS) User Requirements Specifications



[Company Name]
[Company Address]

COMPANY LOGO (?)

User Requirements Specification

[Project Name]

For the Measurement of_____

Author: [Author]
Date: [mm/dd/yyyy]
Version: [#.#]

[Project Name]

Document Control

Document location

Location

Author

Position	Name	Contact no

Revision history

Version	Issue date	Author/editor	Description/Summary of changes

Reviewed by

Version	Issue date	Name	Position	Review date

Approvals

Version	Issue date	Name	Position	Approval date

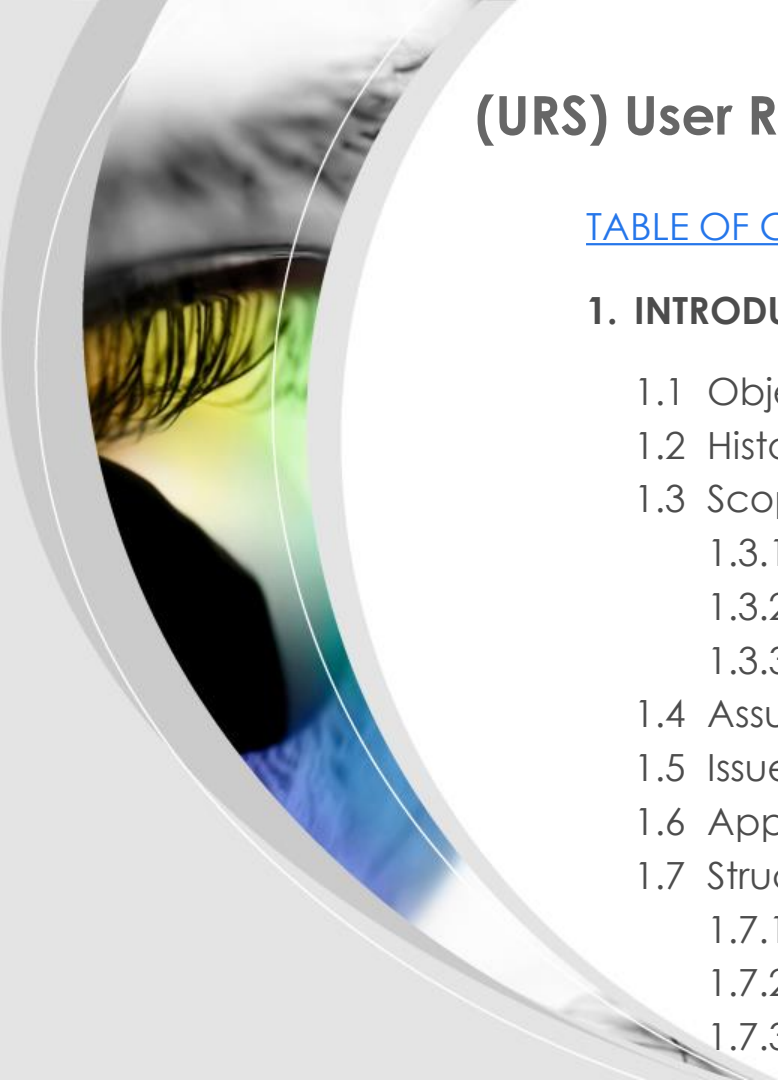
Related documents

Applicable Documents

Document #	Title	Author	Date	Issue

Reference Documents

Document #	Title	Author	Date	Issue



(URS) User Requirements Specifications

HunterLab

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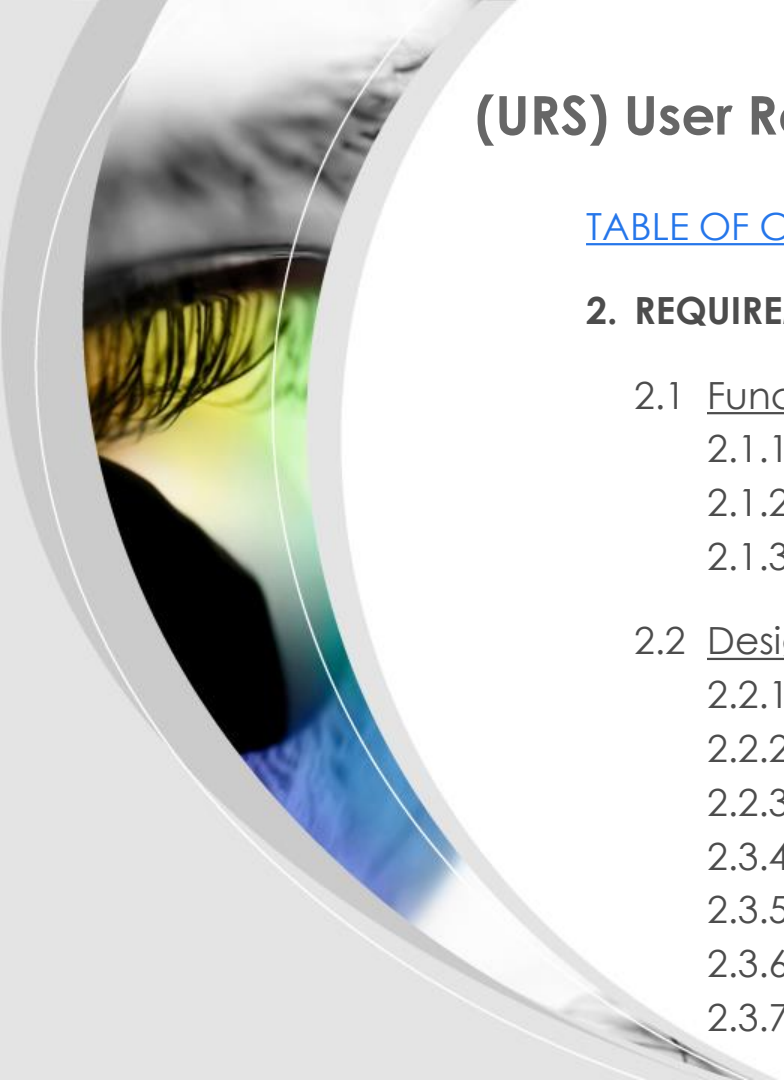

(URS) User Requirements Specifications

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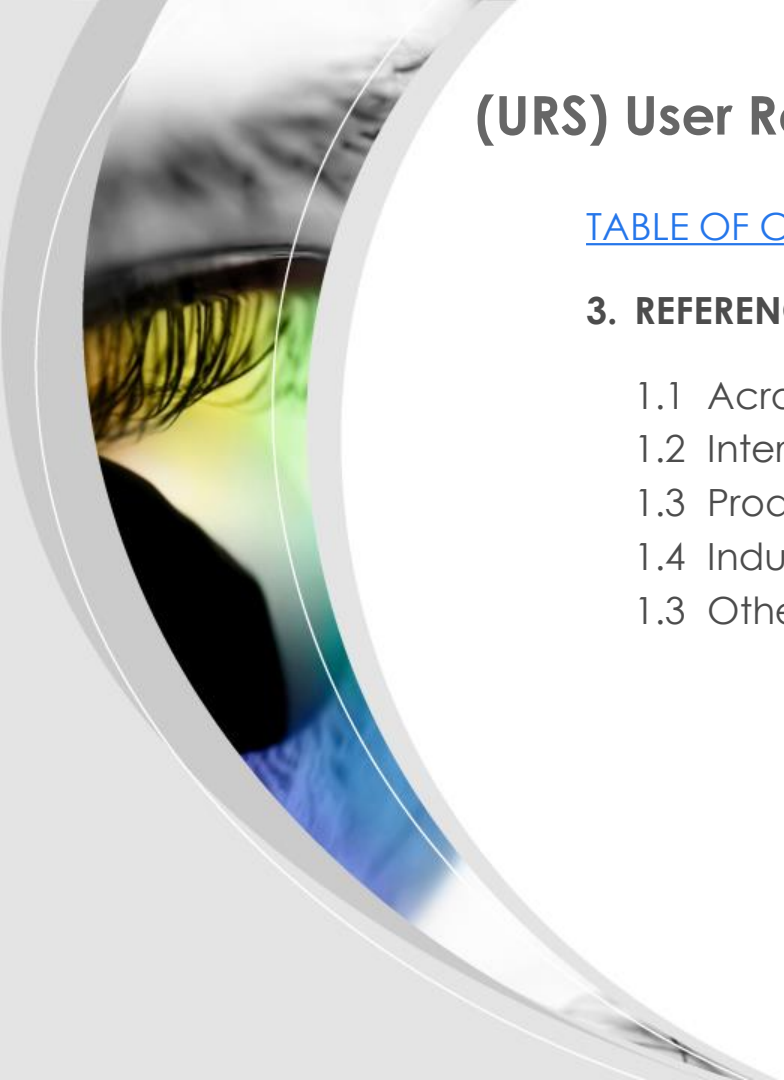

(URS) User Requirements Specifications

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3. REFERENCES

The world's true measure of color

HunterLab

IQ/OQ/PQ/RQ for Color Measurement Instrumentation

Documented testing to confirm proper initial and ongoing Installation, Operation and Performance

Qualification Notebook

- Protocols
- Product/Manufacturer/Type
- Company Info
- Approvals (name/title/signature/date)

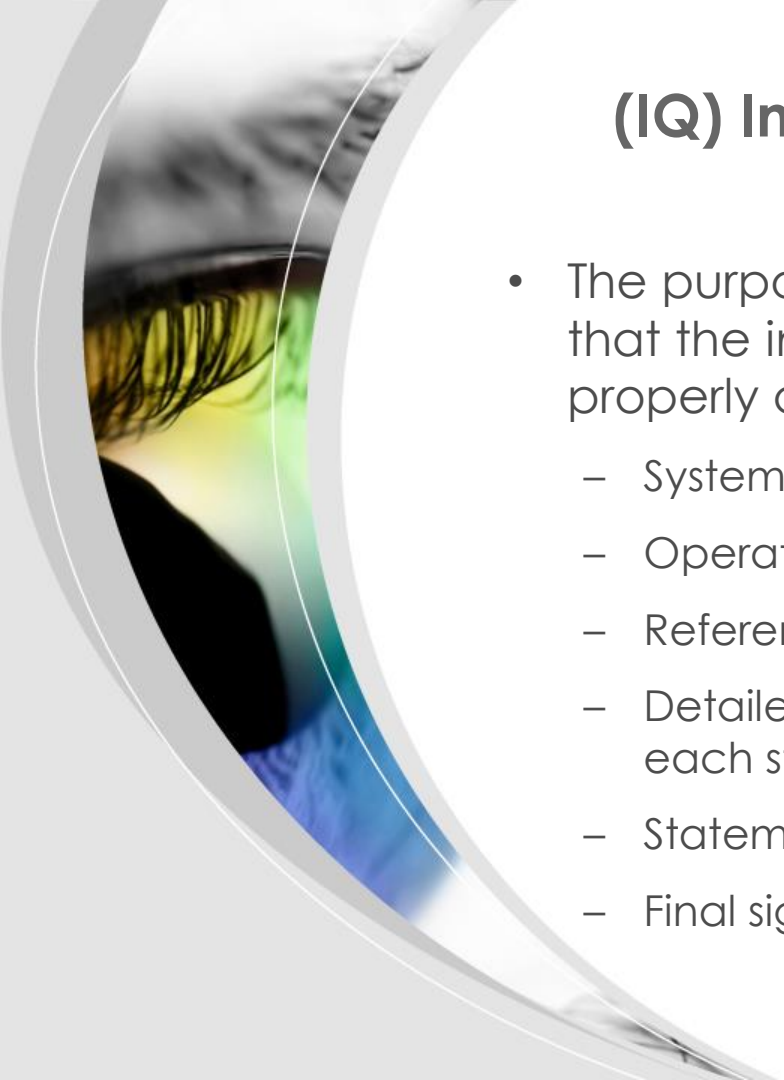
IQ/OQ/PQ/RQ Protocols:

HunterLab UltraScan VIS
Color Spectrophotometer

ABC Company
Address
Date

Approvals

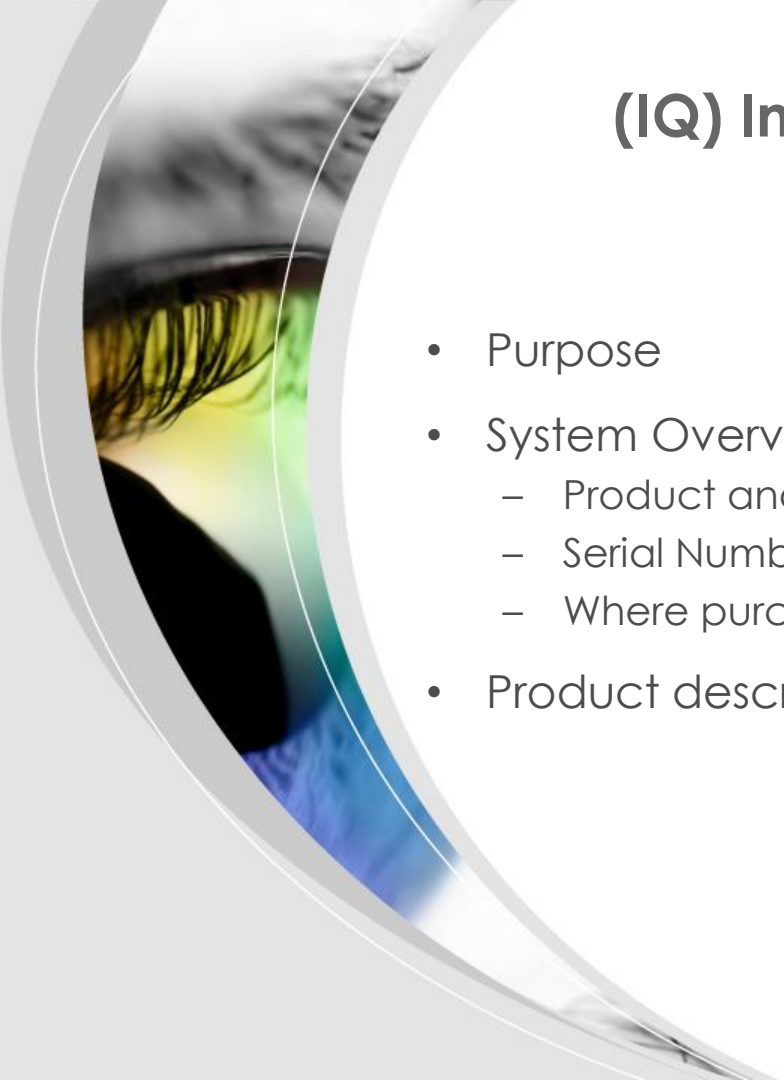
Name/Title	Signature	Date



(IQ) Installation Qualification

- The purpose of this protocol is to ensure and document that the initial installation of the instrument is completed properly and should include:
  - System Overview
  - Operational features and intended use
  - Reference documents
  - Detailed installation procedure with initials and date for each step
  - Statement of Qualification
  - Final sign off of successful Installation Qualification

(IQ) Installation Qualification



- Purpose
- System Overview
  - Product and accessories
  - Serial Numbers/Versions
  - Where purchased
- Product description

IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

I. Installation Qualification Protocol

Purpose

The purpose of this procedure is to ensure that the initial installation of the UltraScan VIS and its optical software are completed properly

System Overview

The UltraScan VIS purchased consists of the following components, which are described in greater detail later in this section and in the UltraScan VIS User's Guide:

- HunterLab UltraScan VIS optical sensor, serial number_____
- EasyMatch QC-ER software, version_____
- Transmission cell holder option
- 10-mm, 20-mm, 33-mm and 50-mm transmission cell holder options
- Holder for small volume transmission cell option
- Small-volume injectable cylindrical sample cell option
- Flow-through transmission cell holder option
- 10-mm, 20-mm and 50-mm flow through cell options
- 4-mm port plate option

These system components were purchased from the following supplier:

Hunter Associates Laboratory, Inc. (also known as "HunterLab")
11491 Sunset Hills Road
Reston, Virginia, 20190 U.S.A.
+703-471-6870
www.hunterlab.com

The UltraScan VIS is a dual beam xenon flash spectrophotometer with a wavelength range from 360 to 780 nanometers (nm). All tristimulus integrations are based on a triangular band pass of ten nm and a wavelength interval of ten nm. The instrument can measure either reflected or transmitted color of product.

The sensor uses a plastic integrating sphere that is six inches (152.4 mm) in diameter and coated with SpectraFlect™, which diffuses the light from the lamp. The light illuminates the sample and is either reflected from it or transmitted through it. A lens located at an angle of 8° collects the light and directs it to a diffraction grating which separates the light into its component wavelengths where they are then measured by a dual diode arrays and converted into usable data

(IQ) Installation Qualification

- Operational Features and Intended Use
- Reference Documents
- Installation Procedures
  - Required Supplies

IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

Operational Features and Intended Use

The UltraScan VIS can be used to measure virtually any type of product. Opaque and translucent materials can be placed at the reflectance port on the front of the sensor for measurement of reflected color. Transparent samples such as films and liquids can be placed in the transmission compartment for measurement of transmitted color.

(Customer) will be measuring the color of liquids and powders used in pharmaceutical manufacturing. This can be expanded to measure the color of slurries and creams with the same methodology.

Reference Documents

The following reference documents concerning the instrument should be kept in a safe place:

- UltraScan VIS users Guide (included with the instrument). Version_____
- EasyMatch QC-ER Users Manual (included with software). Version_____
- Tile Data Sheet
- Certificate of Traceability of the instrument's white tile (included with the instrument)
- CRM-_____ addendum if applicable
- HunterLab's ISO 9001 certification (copy available at our website – www.hunterlab.com

Installation Procedures

Performa the procedures listed below to install the system components and confirm proper installation:

- Procedure 1, attached, provides instructions and a checklist for installation of the system hardware
- Procedure 2, attached, provides instructions and a checklist for installation of the system software

Required Supplies

The following equipment and supplies are required for completion of the Installation procedure

- The UltraScan VIS, its adapter, power cord, communications cable, system computer to which the instrument will be attached, standard 1-inch (25.4 cm) port plate and sample clamp

(IQ) Installation Qualification

- Statement of Qualification
  - Describes the criteria that must be met to deem the instrument properly installed, and remedies if criterion are not met

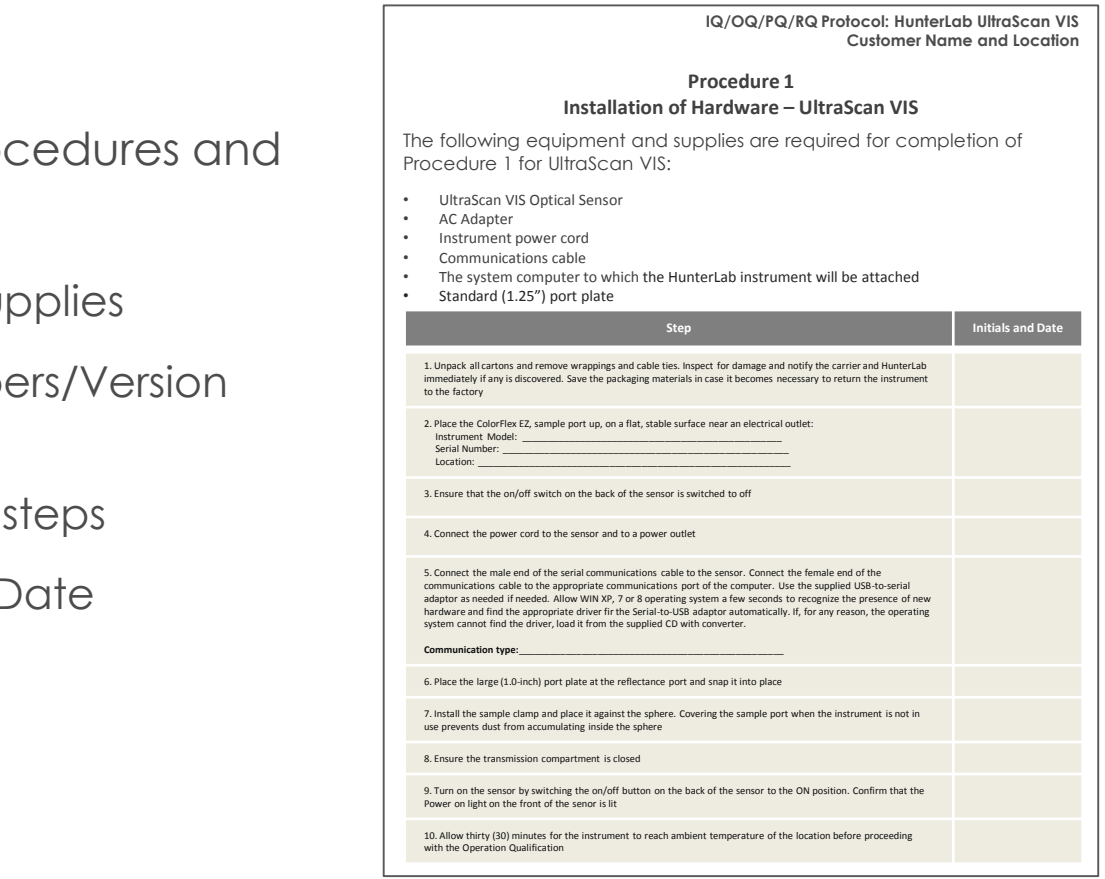
IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

Statement of Qualification

The instrument is deemed to be installed properly so long as Procedure 1 and 2 are successfully completed. If any criterion is not met, the qualification will not proceed and the instrument will not be used for measurements until the point is reconciled, either by maintenance to the instrument or its accessories (such as cleaning tiles) that allows it t pass the failed check or by conversation with HunterLab Technical Support personnel (703-472-6870 or HelpDesk @hunterlab.com)

(IQ) Installation Qualification

- Installation Procedures and checklist
  - Required supplies
  - Serial numbers/Version numbers
  - Procedural steps
  - Initials and Date



IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

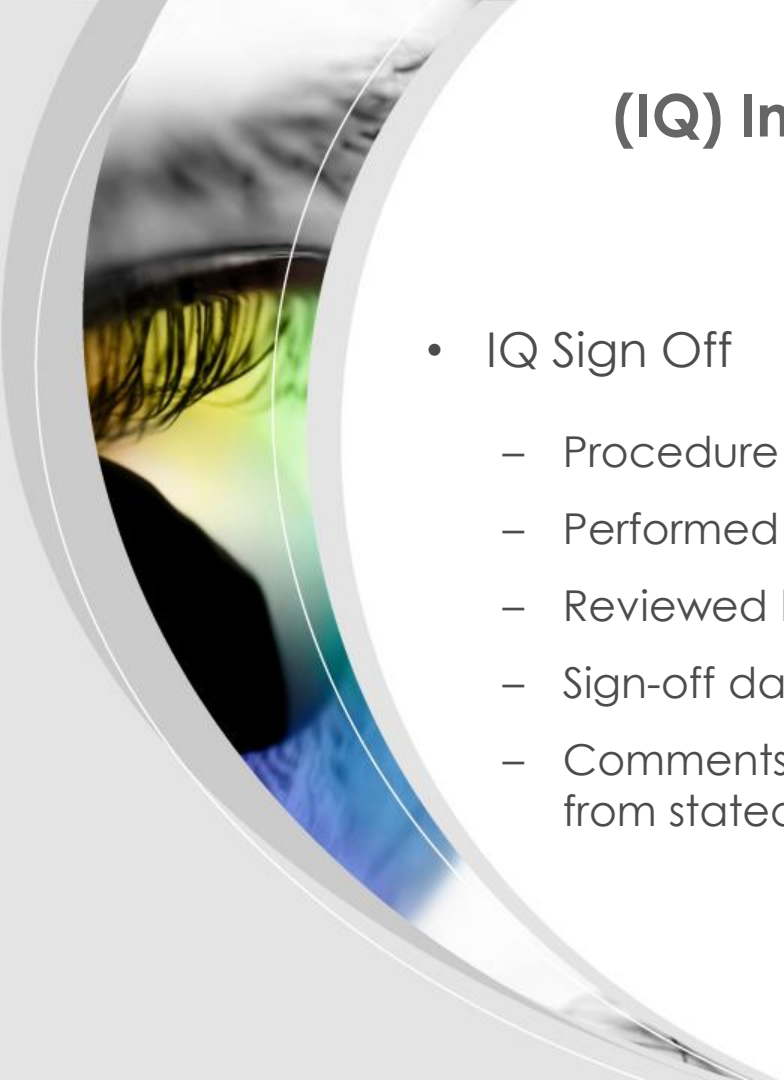
Procedure 1
Installation of Hardware – UltraScan VIS

The following equipment and supplies are required for completion of Procedure 1 for UltraScan VIS:

- UltraScan VIS Optical Sensor
- AC Adapter
- Instrument power cord
- Communications cable
- The system computer to which the HunterLab instrument will be attached
- Standard (1.25") port plate

Step	Initials and Date
1. Unpack all cartons and remove wrappings and cable ties. Inspect for damage and notify the carrier and HunterLab immediately if any is discovered. Save the packaging materials in case it becomes necessary to return the instrument to the factory	
2. Place the ColorFlex EZ, sample port up, on a flat, stable surface near an electrical outlet: Instrument Model: _____ Serial Number: _____ Location: _____	
3. Ensure that the on/off switch on the back of the sensor is switched to off	
4. Connect the power cord to the sensor and to a power outlet	
5. Connect the male end of the serial communications cable to the sensor. Connect the female end of the communications cable to the appropriate communications port of the computer. Use the supplied USB-to-serial adaptor as needed if needed. Allow WIN XP, 7 or 8 operating system a few seconds to recognize the presence of new hardware and find the appropriate driver fir the Serial-to-USB adaptor automatically. If, for any reason, the operating system cannot find the driver, load it from the supplied CD with converter. **Communication type:**_____	
6. Place the large (1.0-inch) port plate at the reflectance port and snap it into place	
7. Install the sample clamp and place it against the sphere. Covering the sample port when the instrument is not in use prevents dust from accumulating inside the sphere	
8. Ensure the transmission compartment is closed	
9. Turn on the sensor by switching the on/off button on the back of the sensor to the ON position. Confirm that the Power on light on the front of the senor is lit	
10. Allow thirty (30) minutes for the instrument to reach ambient temperature of the location before proceeding with the Operation Qualification	

(IQ) Installation Qualification



- IQ Sign Off
  - Procedure(s) performed
  - Performed by
  - Reviewed by
  - Sign-off dates
  - Comments or deviations from stated procedures

IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

Procedure 1, Installation of Hardware - UltraScan VIS, **and Software** – and EasyMatch QC-ER, has been successfully performed as described above

_____ _____

Performed by Date

_____ _____

Reviewed by Date

Comments or deviations from stated procedure:

(OQ) Operational Qualification

- The purpose of this protocol is to confirm that the instrument's measurements meet the manufacturer's specifications to verify instrument performance, and should include:
  - System Overview
  - Operational features and intended use
  - Reference documents
  - Operational Diagnostic Procedures
  - Statement of Qualification
  - Final sign off of successful Operational Qualification

(OQ) Operational Qualification

- Purpose
- System Overview
  - Refer to IQ Protocol
- Reference Documents
  - Refer to IQ Protocol
- Operational Diagnostic Procedures
- Required Supplies

II. Operation Qualification Protocol

Purpose

The purpose of this protocol is to confirm that the instrument meets the manufacturer's diagnostic specifications to verify instrument performance

System Overview

Refer to Installation Qualification Protocol for a system overview

Operational Features and Intended Use

Refer to Installation Qualification Protocol for the instrument's operational features and intended use

Reference Documents

Refer to the Installation Qualification Protocol for a list of required reference documents

Operational Diagnostic Procedures

Performa the procedures listed below to verify Operational Performance of the system:

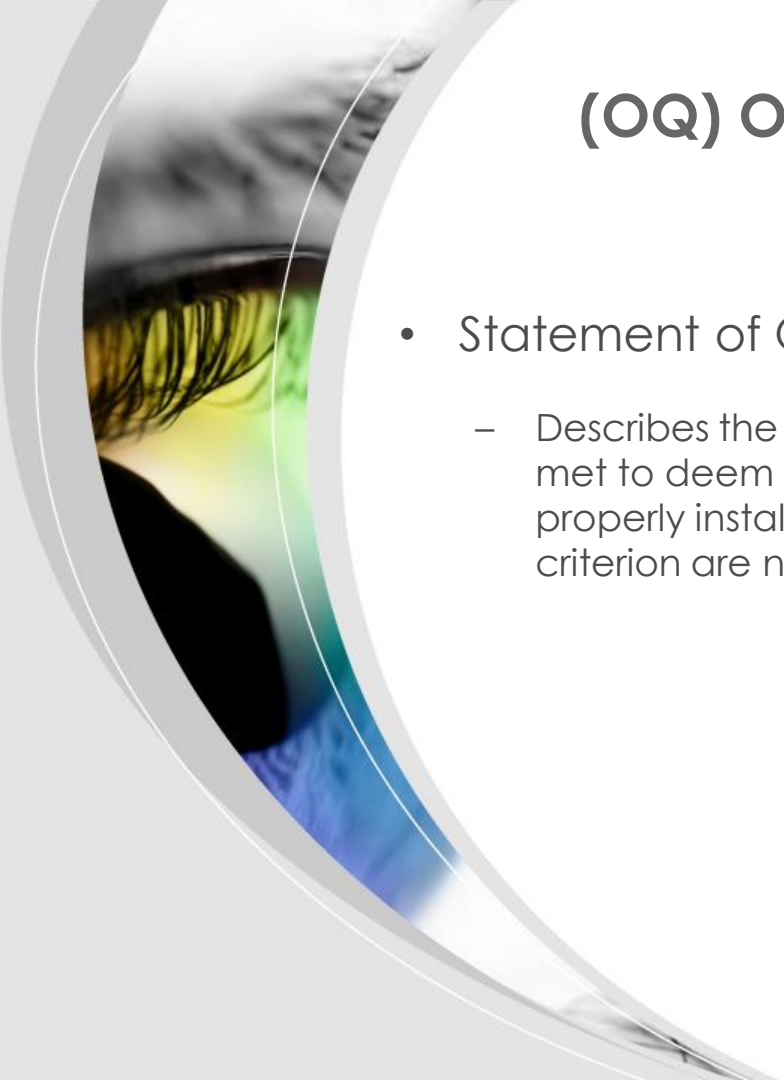
- Procedure 3, attached, provides instructions for checking the instruments short-term repeatability
- Procedure 4, attached, provides instructions for checking the instruments wavelength accuracy
- Procedure 5, attached, provides instructions for checking the instruments mid-range reflectance performance

Required Supplies

The following equipment and supplies are required for completion of the Operational Qualification

- The UltraScan VIS as installed in procedure 1
- The system computer and EasyMatch QC-ER software as installed in procedure 2
- Printer
- Calibrated white instrument standard tile
- Black card device
- Light trap
- Didymium filter
- Green calibrated tile

(OQ) Operational Qualification



- Statement of Qualification
  - Describes the criteria that must be met to deem the instrument properly installed, and remedies if criterion are not met

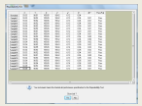
Statement of Qualification

The instrument is deemed to be operating properly so long as the performance specifications for Procedures 3, 4 and 5 are met. If any criterion is not met, the qualification will not proceed and the instrument will not be used for measurements until the point is reconciled, either by maintenance to the instrument or its accessories (such as cleaning tiles) that allows it t pass the failed check or by conversation with HunterLab Technical Support personnel (703-472-6870 or HelpDesk @hunterlab.com

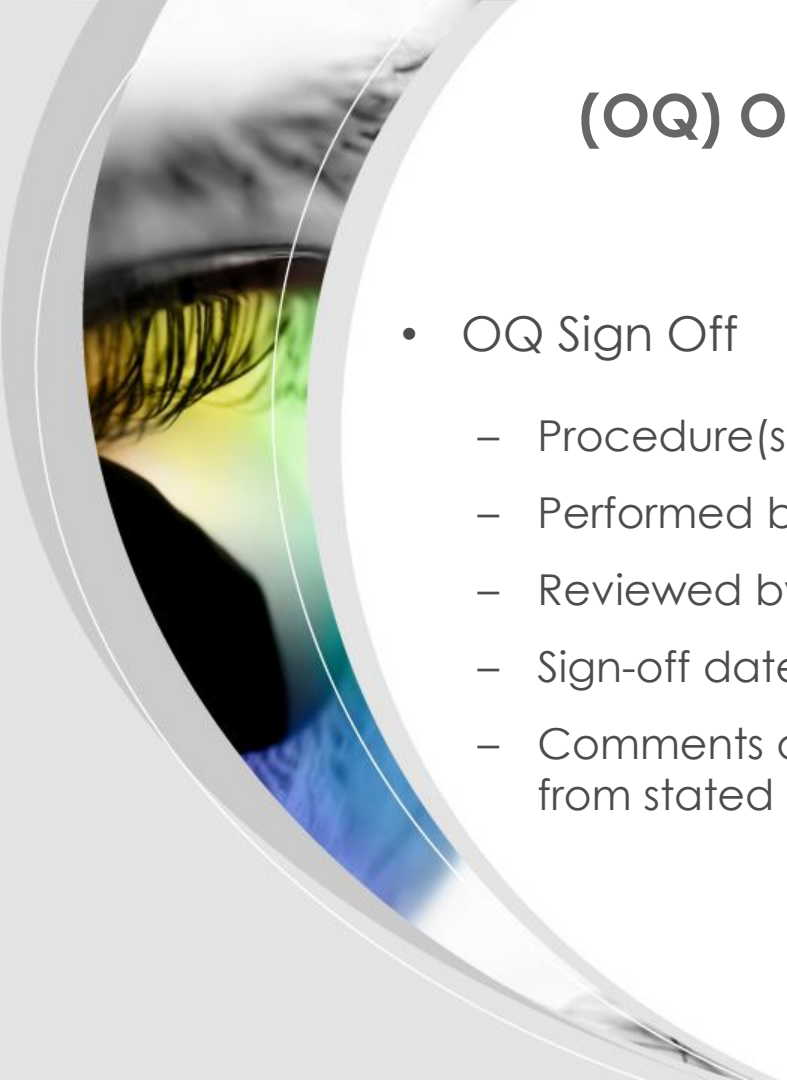
(OQ) Operational Qualification

- Operational Procedures and checklist
  - Procedural steps
  - Initials and Date

IQ/OQ/PQ/RQ Protocols: HunterLab UltraScan VIS Spectrophotometer
Customer Name and Location
8 of 21
Procedure 2
Checking Short-Term Repeatability – UltraScan VIS
This test verifies the short term measurement repeatability of the sensor. If PASS, the sensor electronics are within HunterLab specifications.

Step	Display	Initials and Date
1. From the sensor menu select Diagnostics and then Repeatability Test. A special job is opened in EasyMatch QC-ER software and the following prompt is shown		
2. Install the standard port plate, which is the largest one you have available that is not covered by glass. Click OK when this port plate is installed		
3. Follow the on-screen prompts to perform a normal standardization in RSIN mode. When complete, the following prompt will be shown		
4. Center the calibrated white tile over the reflectance port with the white side facing the instrument. Click OK and the Repeatability Screen will appear		
5. The white tile will be automatically read as the standard followed by twenty more times as samples. PASS/FAIL results for each reading will be displayed.		
6. ER Client\Reports with unique data/time stamp automatically saved for future reference		

(OQ) Operational Qualification



- OQ Sign Off
  - Procedure(s) performed
  - Performed by
  - Reviewed by
  - Sign-off dates
  - Comments or deviations from stated procedures

IQ/OQ/PQ/RQ Protocol: HunterLab UltraScan VIS
Customer Name and Location

Procedure 2, Checking Short-Term Repeatability – UltraScan VIS, has been successfully performed as described above

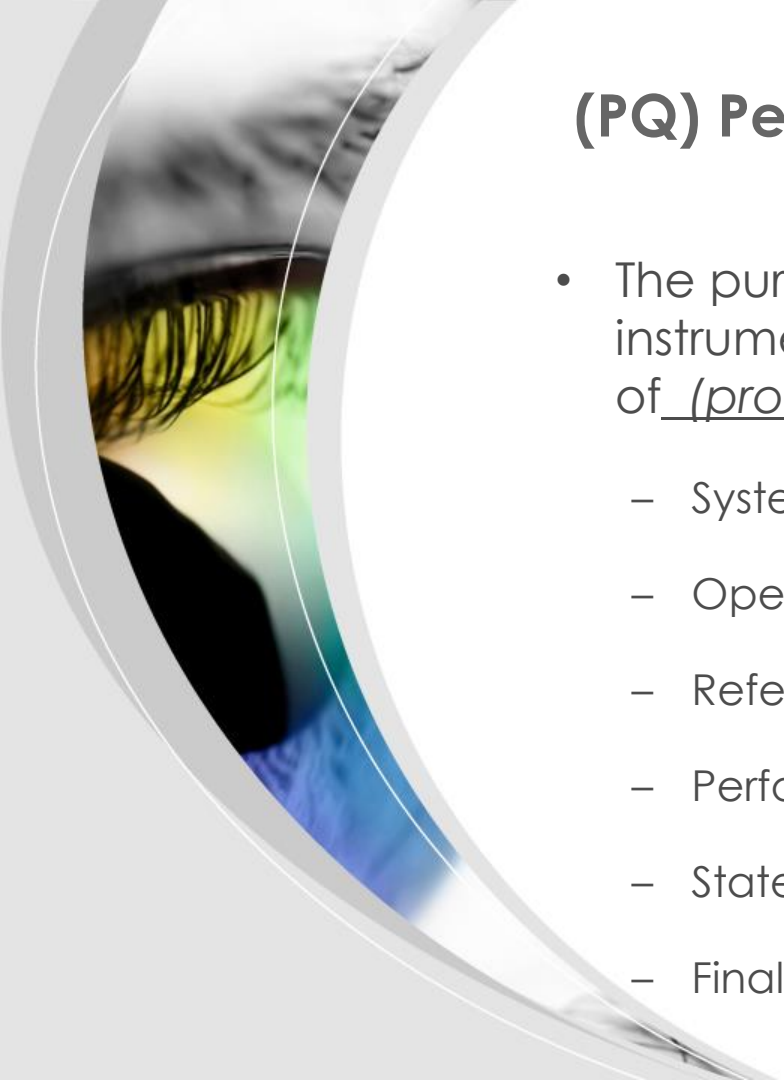
_____ _____

Performed by Date

_____ _____

Reviewed by Date

**HunterLab recommends performing this procedure and recording the results periodically (i.e. weekly or biweekly)*



(PQ) Performance Qualification

- The purpose of this protocol is to confirm that the instrument performs adequately for the measurement of *(product)* .
  - System Overview
  - Operational features and intended use
  - Reference documents
  - Performance Diagnostic Procedures
  - Statement of Qualification
  - Final sign off of successful Operational Qualification

(PQ) Performance Qualification

- Purpose
- System Overview
  - Refer to IQ Protocol
- Reference Documents
  - Refer to IQ Protocol
- Operational Diagnostic Procedures
  - Attachments
  - Required Supplies

III. Performance Qualification Protocol

Purpose

"The purpose of this protocol is to confirm that the instrument performs adequately using the measurement procedures and sample handling devices selected for the measurement of…" and then list your various sample types (i.e.) opaque tablets, transparent liquids, loose powders and translucent creams) here.

System Overview

Might simply refer back to the overview given in the IQ statement, such as:

'Refer to the Installation Qualification Protocol for the instruments operational features and intended use"

Refer to Installation Qualification Protocol for a system overview
Might simply refer back to the overview given in the IQ statement, such as:

Operational Features and Intended Use

"Refer to the Installation Qualification Protocol for the instruments operational features and intended use"
Refer to Installation Qualification Protocol for a list of required reference documents

Performance Diagnostic Procedures

Perform the procedures listed below to verify performance of the system using the measure that will be used for the samples:

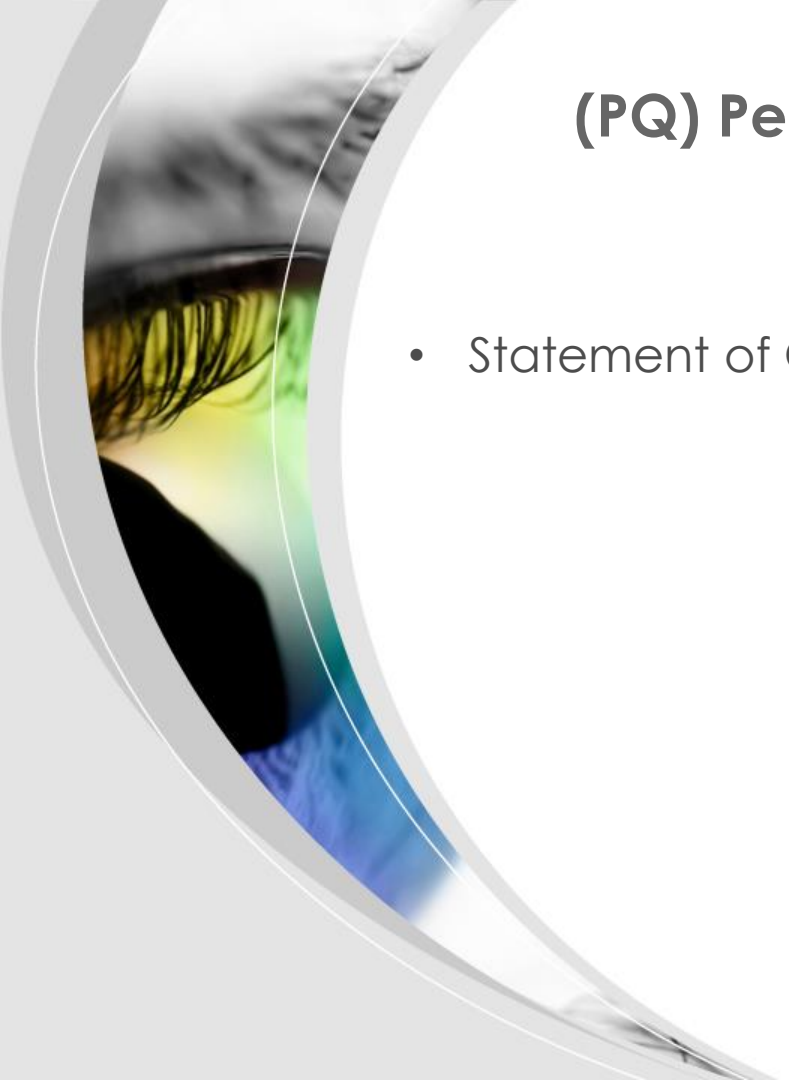
- Procedure 4, attached, provides instructions for checking the instruments measurement performance using the appropriate procedures for measuring the whiteness and color of powder products

Required Supplies

The following equipment and supplies are required for completion of the Performance Qualification:

- The ColorFlex EZ meter as installed in procedure 1
- The calibration instrument White Tile
- The black glass
- 2.5 inch Glass Sample Cup 04-7209-00
- Port inert for Sample Cup 04-6622-00
- Sample Cup Opaque Cover 04-4000-00
- USB Adapter Cable A13-1014-375 if entering ID's from keyboard
- USB Flexible Keyboard A13-1014-294 to enter Product ID's
- USB Printer A13-1014-259 to print hard copy records of the measurements

(PQ) Performance Qualification

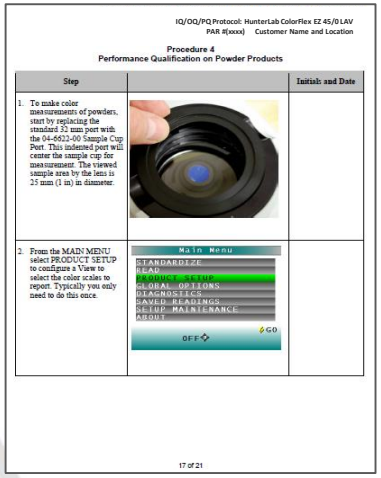


- Statement of Qualification

Statement of Qualification

This instrument and method are deemed to be performing properly so long as the performance specification for Procedure 4 is met. If this criterion is not met, the instrument will not be used for measurements until the point is reconciled, either by maintenance to the instrument or its accessories (such as cleaning tiles) that all0ows it to pass the failed check or by communication with HunterLab Technical Support personnel (703-472-6870 or HelpDesk @hunterlab.com)

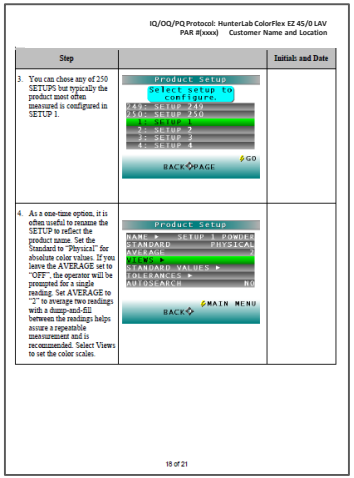
(PQ) Performance Qualification



IQ/OQ/PQ Protocol: HunterLab ColorFlex EZ 45/0 LAV
PAR #(xxxx) Customer Name and Location

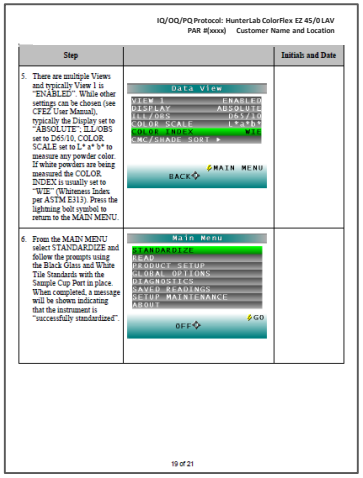
Procedure 4
Performance Qualification on Powder Products

Step		Initials and Date
1. To make color measurements of powders, start by replacing the standard 23 mm port with the 04-6622-00 Sample Cup Port. This indented port will center the sample cup for measurement. The viewed sample area by the lens is 25 mm (1 in) in diameter.		
2. From the MAIN MENU select PRODUCT SETUP to configure a View to select the color scales to report. Typically you only need to do this once.		



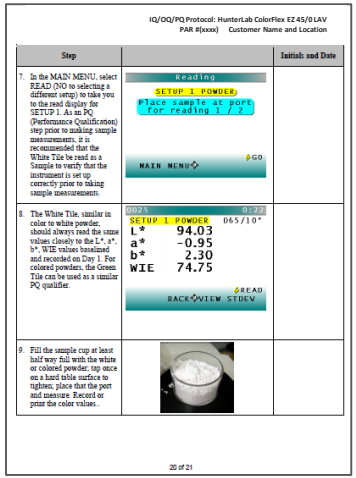
IQ/OQ/PQ Protocol: HunterLab ColorFlex EZ 45/0 LAV
PAR #(xxxx) Customer Name and Location

Step		Initials and Date
3. You can chose any of 250 SETUPS but typically the product most often measured is configured in SETUP 1.		
4. As a one-time option, it is often useful to rename the SETUP to reflect the product name. Set the Standard to "Physical" for absolute color values. If you leave the AVERAGE set to "OFF", the operator will be prompted for a single reading. Set AVERAGE to "2" to average two readings with a dump-and-fill between the readings helps assure a repeatable measurement and is recommended. Select Views to set the color scales.		



IQ/OQ/PQ Protocol: HunterLab ColorFlex EZ 45/0 LAV
PAR #(xxxx) Customer Name and Location

Step		Initials and Date
5. There are multiple Views and typically View 1 is "ENABLED". While other settings can be chosen (see CFEZ User Manual), typically the Display set to "ABSOLUTE", ELOBS set to D65/10, COLOR SCALE set to L* a* b* to measure any powder color. If white powders are being measured the COLOR INDEX is usually set to "WIE" (Whiteness Index per ASTM E313). Press the lightning bolt symbol to return to the MAIN MENU.		
6. From the MAIN MENU select STANDARDIZE and follow the prompts using the Black Glass and White Tile Standards with the Sample Cup Port in place. When completed, a message will be shown indicating that the instrument is "successfully standardized".		



IQ/OQ/PQ Protocol: HunterLab ColorFlex EZ 45/0 LAV
PAR #(xxxx) Customer Name and Location

Step		Initials and Date
7. In the MAIN MENU, select READ (NO to selecting a different setup) to take you to the read display for SETUP 1. As an PQ (Performance Qualification) step prior to making sample measurements, it is recommended that the White Tile be read as a Sample to verify that the instrument is set up correctly prior to taking sample measurements.		
8. The White Tile, similar in color to white powder, should always read the same values closely to the L*, a*, b*, WIE values baselined and recorded on Day 1. For colored powders, the Green Tile can be used as a similar PQ qualifier.		
9. Fill the sample cup at least half way full with the white or colored powder, tap once on a hard table surface to tighten, place that the port and measure. Record or print the color values..		

(PQ) Performance Qualification

Final sign off

Procedure 4, Checking the Instruments Performance on (powder) products, has been successfully performed as described above

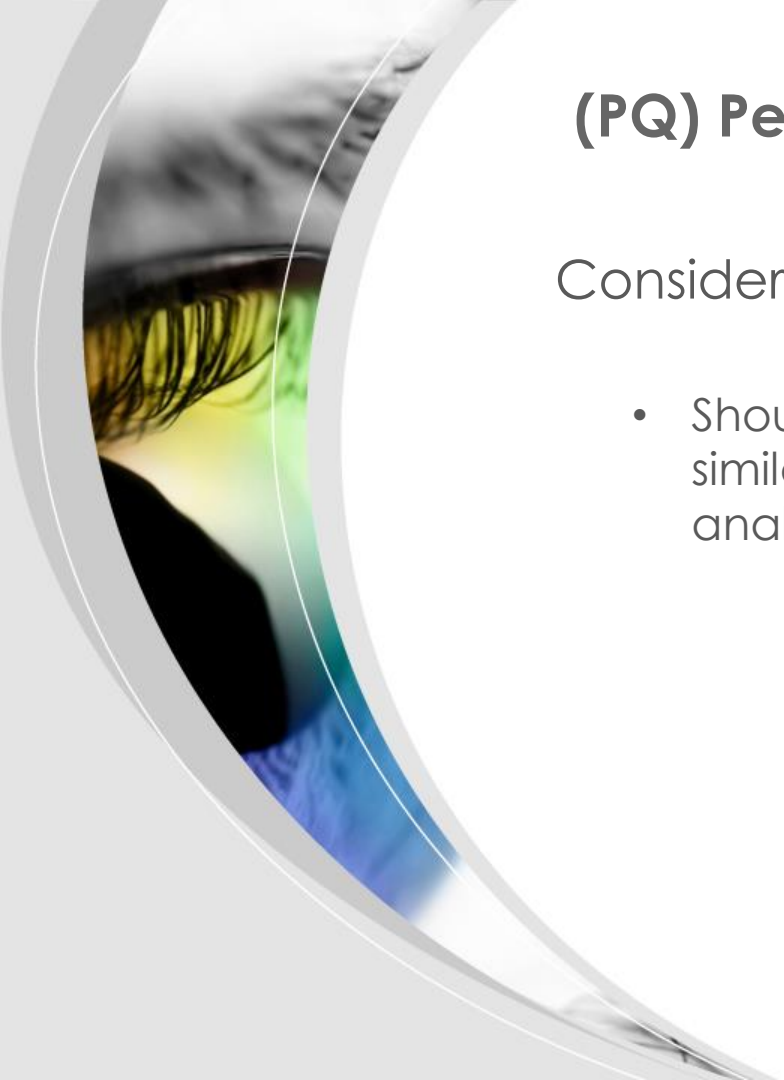
_____ _____

Performed by Date

_____ _____

Reviewed by Date

Comments or deviations from stated procedure:



(PQ) Performance Qualification

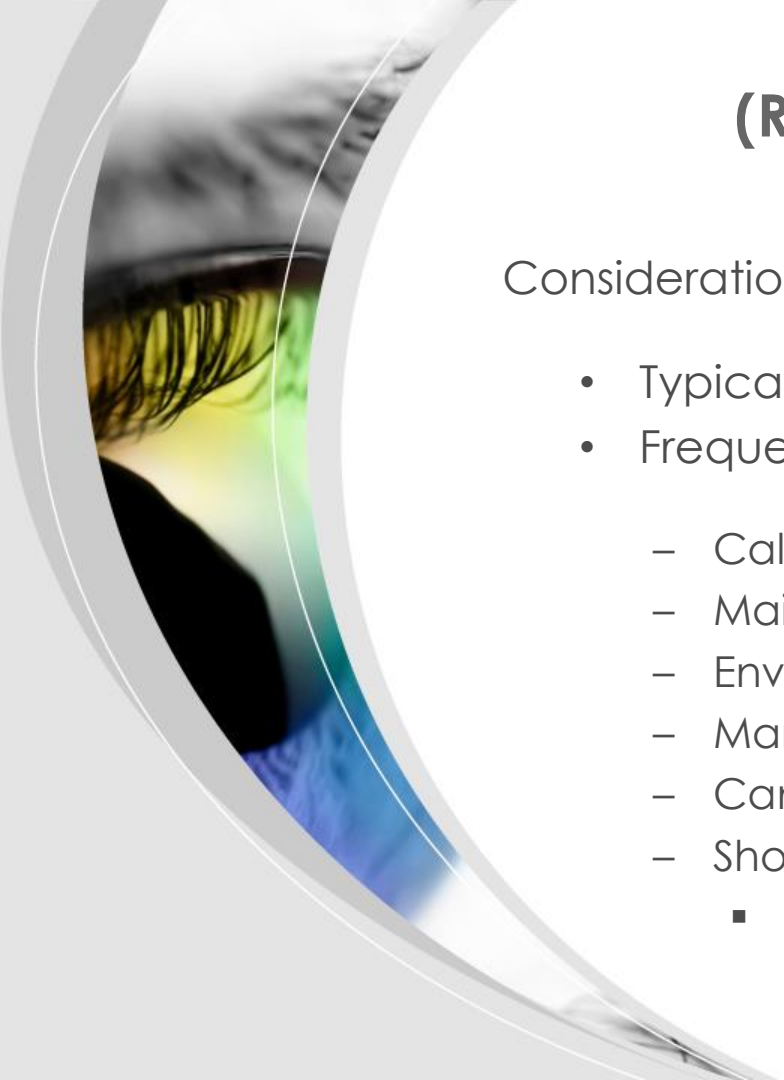
Considerations:

- Should be performed under conditions that are similar to the environment where routine sample analysis is performed

(RQ) Requalification

Requalification validates that the equipment is still in qualified state after a change AND periodical assessment within defined time intervals:

- Describe and document any maintenance required on the equipment
- Detail any maintenance contracts together with a list of authorized service agents
- Include and document routine cleaning and calibration of the equipment
- Include and document annual factory maintenance and recertification and requirements
- Hardware/Software System Validation checklists



(RQ) Requalification

Considerations:

- Typically follow OQ/PQ processes
- Frequency based on a determination of:
  - Calibration / Verification results
  - Maintenance history
  - Environment
  - Manufacturers recommendations
  - Can be periodic (with a defined schedule)
  - Should always be done after a change
    - Part of Change control procedure

The world's true measure of color

HunterLab

IQ/OQ/PQ/RQ for Color Measurement Instrumentation

Recording Instrument History, and Audit Trails

Recording Instrument History

Instrument history records are not the same as audit trail records, they document:

Purchase

- Purchase Date
- Where Purchased
- Serial Numbers
- Software Versions
- Maintenance Contracts
- Cleaning/Calibration Schedule

Pre Use

- Initial IQ/OQ/PQ Records and Signoff's

Post Use

- RQ records
- Maintenance records:
  - Calibration/validation history (can be electronically generated)
  - Cleaning and Maintenance logs
  - Factory Service Logs
  - Factory Repair Logs

POLL QUESTION

- Do you currently use a logbook or other instrument qualification documentation method?

☐ YES

☐ NO

IQ/OQ/PQ/RQ Protocols:

HunterLab UltraScan VIS
Color Spectrophotometer

ABC Company
Address
Date

Approvals

Name/Title	Signature	Date

Audit Trails

- **Purpose:** To provide assurance of the integrity and trustworthiness of the Electronic Record and the associated Raw Data
- A **regulatory expectation** where data is stored and has the facility to be changed, modified or deleted *(i.e. 21 CFR 11 §11.10€: Audit Trail; EU GMP Annex 11, Clause 9: Audit Trail)*
- Impacts both the **computer controlled automated system** and **laboratory systems** used within the Food and Pharmaceutical industries
- Must include a process for reviewing the audit trail for assuring the record integrity

Audit Trails

- Should be linked to the electronic record
- Should be secure and not be able to be edited or deleted, providing a permanent record
- Should record for each entry:
  - Date and Time Stamp
  - Link to the record (Batch No,. Record ID)
  - Original Value
  - *Changed Value
  - *Reason for Change
  - *Name and User making the change (unique ID)

*Some electronic systems do not enable changes. They allow user to retake a measurement but not change a previous record.

SUMMARY

- Instrument Qualification a critical part of a Validation Process
- It starts ***Pre-Purchase*** with clear and concise User Requirements Specifications ***and*** the right product for the job at hand
- IQ/OQ/PQ are ***Pre-Use*** qualification steps that ensure the instrument is *properly received, properly installed*, and *operating* and *performing* to specifications
- RQ is done ***Post-Use*** and should be performed at minimum as part of a change control process
- Keep a Logbook to document all activities from URS to RQ
- Remember – recording Instrument History is not the same as Audit Trails

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Thank You

For more information about HunterLab please visit:

www.hunterlab.com

*Or visit us at **AAPS 2014** or **PittCon 2015***