PDHonline Course K111 (4 PDH)

Creating a Pharmaceutical Installation Qualification

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Creating a Pharmaceutical Installation Qualification

W.N. Weaver PE

Course Content

INTRODUCTION

Pharmaceutical Validation is a growing field for engineers. Not only is validation an FDA requirement, several states have determined that the process of validation falls under the heading of engineering and as such requires the supervision of a registered professional engineer if performed by other than plant personnel.

Validation of a pharmaceutical facility occurs in several stages. Depending on the operational status of the facility we can choose one of three types of validation:

Retrospective Validation:	Validation of an existing facility based on significant accumulated production data.
Concurrent Validation:	Validation of a facility while production is underway.
Prospective Validation:	Validation of a facility, which is in the final stages of construction or just ready to start production. This is the most common type of validation and will be the one considered in this course material.

Validation is accomplished through the use of Protocols, which are designed to test certain aspects of the Installation, Operation and Performance of the equipment or process. With the exception of the Installation Qualification, each protocol contains a series of scientifically sound operational tests to evaluate the equipment or process.

The validation process varies somewhat from company to company. This is generally reflected in the content of protocols and occasionally in the number or type of protocols. The content of this course has been developed to include all items normally found in an Installation Protocol. Deletion of some sections or additions specifically matching the needs of the company is acceptable and the responsibility of the pharmaceutical company.

PROTOCOLS

Before we begin study of the Installation Protocol we need to understand the relationships between the various protocols.

Design Qualification (DQ)	An analysis of the design for compliance with the required process. If performed would be the first protocol in the series.
Installation Qualification	An analysis of the installation of a piece of equipment to

(IQ)	ensure the installation meets the manufacturer's instructions and the process design.
Operational Qualification (OQ)	A series of tests designed to determine if the equipment operates in accordance with the manufacturer's statements, the purchase specification and the process design.
Performance Qualification (PQ)	A series of tests designed to determine if a process stream (which could consist of one machine only) operates in accordance with the process design.

Creation of the protocols above is generally in the order shown. A DQ is not a common protocol as of this writing but is beginning to become popular. Each protocol builds on the previous protocol. Before you verify proper operation of a piece of equipment (OQ) it is logical to confirm proper installation (IQ).

The content of this course covers the mechanical aspects of the Installation Qualification. In the case of equipment with computer, PLC or DCS control these components are covered in the Automation Installation Qualification, AIQ.

A quick listing of protocols:

DQ	Design Qualification
IQ	Mechanical Installation Qualification
AIQ	Automation Installation Qualification
OQ	Operational Qualification
AOQ	Automation Operational Qualification
PQ	Performance Qualification
PV	Process Validation
CQ	Cleaning Qualification

GENERAL ITEMS

All protocol pages are numbered, have a "Header" which lists the company and location, identifies the type of protocol, the equipment for which the protocol is written, and the document number.

Depending on the company the first page (Approval Page) may or may not be numbered and usually will not show the header. Numbering provides the FDA with assurance that no pages with failing data were removed and ensures that all pages in the original document are present.

Sample Header for pages 2 and following.

XYZ Pharmaceuticals 610B Minuet Lane Grand Rapids, MI	INSTALLATION QUALIFICATION for The FA AUTOCLAVE	Document #: AFIQ Page X of Y

All protocols also have two signature lines on the bottom of most pages, shown below. Depending on the format used the "Executed By" and Reviewed By" lines may appear after each test function or data recording activity as opposed to the end of each page.

Executed By: _____Date: _____

Reviewed By: _____ Date: _____

THE CONTENT OF AN INSTALLATION QUALIFICATION (IQ)

The intent of the IQ is generally stated as being the verification of the installation. This is somewhat of a simplification. The following are the basic contents of the IQ. Each section will be reviewed in detail as we move along.

1. APPROVAL PAGE
2. TABLE OF CONTENTS
3. SIGNATURE PAGE
4. GENERAL
5. PURPOSE / SCOPE OF PROTOCOL
6. SYSTEM DESCRIPTION
7. RESPONSIBILITIES
8. EXECUTION PROCEDURES
9. DOCUMENTATION
10. TEST EQUIPMENT
11. VISUAL INSPECTION
12. EQUIPMENT COMPONENTS
13. INSTRUMENTATION
14. UTILITY VERIFICATION
15. SUMMARY REPORT
16. APPROVAL PAGE

1. APPROVAL PAGES

Approval for a specific document is a matter of choice by the company, as long as those individuals providing approval have the authority and knowledge necessary to achieving the goal of maintaining quality, efficacy and purity.

There are two approvals for each protocol: initial approval and execution approval. Approvers vary from facility to facility but as a general rule are the following individuals:

Quality Assurance Manager
Production Manager
Engineering Manager

Regulatory Affairs Manager
Validation Manager

Frequently facilities are not large enough to have all of these positions; that is not a problem as long as those in “responsible charge” of the facility are approving the protocol.

Likewise some facility managers do not have time to read and approve each protocol, in these cases the manager may designate someone to use his authority for review and approval. If this is a temporary assignment and not part of the normal facility organizational structure then a letter of authorization from the manager should be placed in the validation files for the equipment or process represented by the protocol.

1A. INITIAL APPROVAL

This approval page is generally the cover page of the document and approvals represent a review and acceptance of the content of the protocol; it signifies that the appropriate individuals have reviewed the protocol and have determined that it indeed provides adequate details about the equipment and installation. There will also be a signature line for the individual preparing the protocol. See Attachment A for a sample of this document.

First Rule: No protocol may be executed without all required approvals.
Second Rule: Field execution of the protocol is done on a COPY of the approved protocol. Generally stamped COPY on each page.

1B. EXECUTION APPROVAL

This approval page is generally the last page in the protocol and represents a review of the executed document for consistency and completeness. It is essentially a verification that all of the testing was done per the requirements of the protocol and their signatures are an acceptance of that execution. The original signers or newly designated individuals from the same departments as the original approvals are required. See Attachment B for a sample for this document.

2. TABLE OF CONTENTS

Generally self-explanatory and there are no differences in its usage in a validation protocol.

Protocol content and arrangement are not specified by the FDA or any other regulatory body. The intent of validation is proof of consistency in production and control of the operations to the extent necessary to maintain product quality, purity and efficacy. Therefore to this end there are as many acceptable protocol arrangements as there are pharmaceutical companies.

The order of appearance of items within the protocol mimic the contents listing of the contents of this course. They are generally covered in this order: General Information, Procedures, Tests, and Approval.

3. SIGNATURE PAGE

This is simply what it says, a page showing the signature and position of each person approving, executing or reviewing the protocol. All persons who will or have written in the executed protocol, including Approval pages, must complete this signature page. Identification of individuals is provided in three formats

Printed or typed
Signature
Initials

XYZ Pharmaceuticals 610B Minuet Lane Grand Rapids, MI	INSTALLATION QUALIFICATION for The FA AUTOCLAVE	Document #: AFIQ Page X of Y

SIGNATURE PAGE				
Name	Title	Company	Signature	Initials
Charlie Weaver	Validation Engr.	XYZ Pharma		

COMMENTS: Use this section to explain that Mr. Smith, QA Manager, has delegated signature authority for this document to Mrs. Jones. This statement is in addition to the file letter mentioned above.

Reviewed By: _____ Date: _____

There is no “Executed By” line since we’re getting signatures. However someone should review this page to ensure that all necessary signatures and initials are present. The first three columns may be typed in but the last two must be a valid signature and initial.

4. GENERAL

If present this section details how the overall validation effort will be accomplished, how this protocol fits into the Master Validation Plan and what the schedule for completion of the total validation effort will be. Unless the company requires this section it is generally not used.

5. PURPOSE / SCOPE OF PROTOCOL

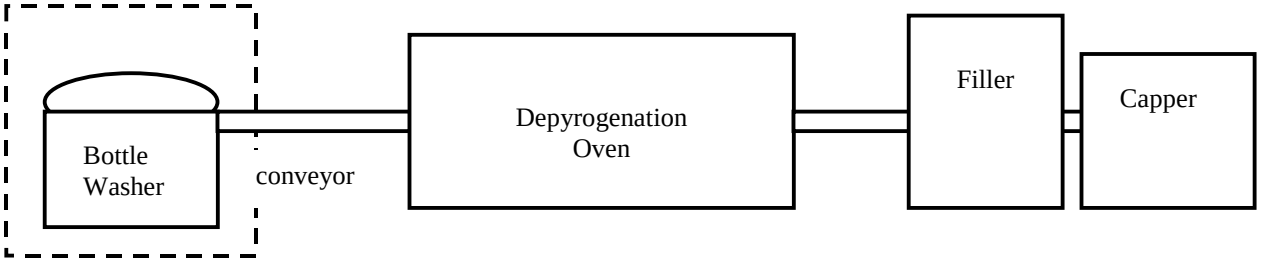
Two common names for essentially the same information.

Here we are detailing the reasons for the protocol; everyone already knows from the title and some companies have deleted this paragraph. We are intending to prove that the equipment has been properly installed and at the conclusion of this IQ will be ready for testing under the OQ. A sample paragraph follows.

"This protocol provides testing and documentation to indicate proper installation in agreement with the manufacturer's recommendations and the intent of the design. Adequate documentation exists to ensure continued proper operation to ensure quality, efficacy and purity of the product."

Within this series of paragraphs we describe the "boundary limits" for the protocol. As an example suppose you have a bottle washer in line with a depyrogenation oven (destroys bacterial body parts) which is in line with a bottle filling machine and capper. See Sketch

Boundary limits



We only want this protocol to refer to the Bottle Washer so we verbally describe the boundary limits of the protocol. In complicated situations you may want to refer to a specific drawing (P&ID or Equipment Arrangement) which has been marked to show the boundary and is kept on file with the validation protocols. Generally you would not attach the drawing to the protocol. Following is a sample paragraph.

"This protocol will examine the Bottle Washer, Number ABC (equipment number) and related utilities. Utility connections will be verified but will be tested under a separate protocol. This Installation Qualification will verify the mechanical equipment and components; verification of the control system will be found in a separate document titled "AIQ for The Bottle Washer, Number ABC".

Additional restrictive comments may be added as necessary to limit the scope of work to this particular piece of equipment. Generally the scope should include any part of the equipment line that was supplied with the bottle washer. For instance the output conveyor from the bottle washer would most likely have come with the washer and thus should be part of the system.

As a general rule ALL components of a process stream must be included in the protocols so even if the output conveyor came from another source if it logically fits into the protocol for the washer that is where it should be.

6. SYSTEM DESCRIPTION

Although this may contain some of the information from the Scope of Work section it goes into much more detail. As a guide this section contains paragraphs covering the following:

Equipment Location: Generally the name and address of the facility along with the location of the equipment within the facility.

"Bottle Washer ABC is located on the premises of XYZ Pharmaceuticals located at 610B Minuet Lane, Cedar Rapids, Michigan in Building 101 on the second floor of production unit Number 2."

Equipment Function: A descriptive paragraph giving the basic purpose and capacity of the equipment.

"Bottle Washer ABC is manually fed and discharges by an automated conveyor system into the Depyrogenation Oven, DEF. The unit is manufactured by the My Washer Company of Dearborn, IL and is a model 1410.
The unit is a vertical bottoms up washer utilizing hot Water For Injection for washing and heated sterile air for drying. The unit is capable of washing bottles in the size range from 10 milliliters to 1 liter at rates varying from 180 per minute to 40 per minute respectively. Bottles are inverted from the feed table, washed, dried and re-inverted to feed the Depyrogentation Oven DEF."

Utility Requirements: Here we want a brief description of what utilities are required for proper operation.

"Bottle Washer ABC requires electrical power at 240 volts, hot Water for Injection at 140 ºF, sterile air at 60 ºF, connection to a process sewer and installation in a Class 1000 classified environment."

7. RESPONSIBILITIES

Here the major players in the validation activity are detailed along with what they are responsible for in the validation effort. Generally you will not list individuals, however, all applicable departments are listed. Not all of the "departments" listed will be part of the facility since a large percentage of validation is provided by outside companies.

Contractors:	Prepare and execute validation protocols under the direction of the Validation Department of XYZ Pharmaceuticals.
Validation Department:	Supervise preparation of protocols, approve protocols for execution and review executed protocols for approval.
Engineering Department:	Ensure all equipment is properly installed and operational for protocol execution. Provide technical support to validation engineers as required. Approve protocols for execution and approve executed protocols.
Regulatory Affairs Department:	Provide training in plant SOP's as required for operating personnel and validation engineers. Approve protocols for execution and approve executed documents.
Quality Assurance Department:	Provide testing of samples as required during protocol execution through the QC labs. Approve protocols for execution and approve executed documents.
Production Department	Provide trained operating personnel, necessary supplies and process materials as needed for the validation effort. Approve protocols for execution and approve executed documents.

Depending on the structure of the company and the departments available this list can grow but would most likely not shrink. Additions and deletions for specific protocols occur. It is not unusual to see Maintenance included with equipment such as Pure Steam Generators and Water For Injection systems. The IT department is usually added if the system is controlled by computers, DCS or PLC's.

Maintenance Department:	Ensure all equipment has been serviced and that all critical instruments have been calibrated. Support Contractor's validation engineers.
IT Department:	Ensure all computer control systems are functional and that backup software is available. Support Contractor validation engineers as needed.

Third Rule: Protocol approval must include those responsible for systems operation.

8. EXECUTION PROCEDURES

This section details how the protocol is to be executed. There are some peculiarities with each company but the following are generally accepted guidelines. A short paragraph covering each item is the accepted format.

A. Training of the validation engineer in SOP's for specific equipment although not always required is generally a sound plan. The FDA inspectors tend to think it is best if the person doing the execution understands the purpose of the equipment and in protocols requiring equipment operations this makes sense.

"Prior to commencing protocol preparation the validation engineers will be trained by appropriate plant personnel in the following SOP's: "Validation Document Preparation, VD-111", "Validation Protocol Execution, VD-112", "Operation of Bottle Washers, BW-140", "Gowning Procedure for Classified Areas, GP-150".

B. Recording of data in the protocol is always in ink, always in a **copy** of the approved protocols and always by the person(s) doing the execution. Some companies will require only blue ink (from the days when copiers couldn't copy blue) and some will require black ink. Ink smears, wrinkles and stains are an indication to the FDA that the execution occurred in the field and not at the desk.

"All execution data is to be recorded in black ink using a standard ball point pen. Pencil, felt tip pens and similar markers are prohibited."

C. Correction of data entry errors always seems like a big deal and something to be avoided. However, an executed protocol without some data entry error is suspect. In this paragraph detail how data entries are to be corrected.

Protocol Instructions (each "test" within a protocol will have an instruction set generally on the page where the data is to be recorded, the following is an excerpt from such an instruction set)

Record the Serial Number of the equipment SN 78349 WNW / 1/20/04

The actual number should be SN 87349

Corrected data is entered as follows:

WNW 1/20/04
Record the Serial Number of the equipment ~~SN 78349~~ SN 87349 WNW 1/20/04

Normal Paragraph

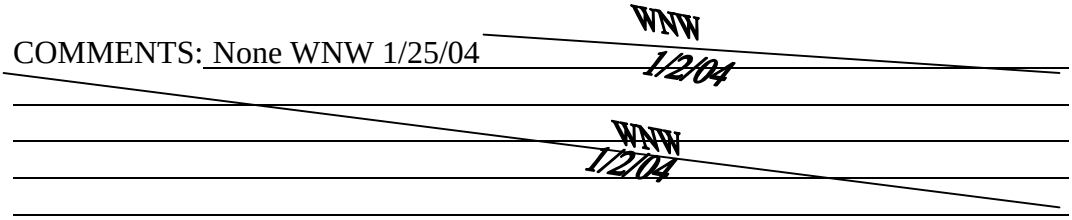
"Data entry errors are to be corrected by striking through the incorrect data with a single line and recording the correct information along with your initials and the

date. Under no circumstances is data to be "scribbled" through or totally obliterated, no "white out" is allowed."

Fourth Rule: Data entry is corrected in such a manner that the erroneous data is legible. Always initial and data corrections. Corrections to data entry may be made by the protocol reviewer or other authorized person.

D. Frequently you will find (or create) spaces for COMMENTS and other data entry where nothing is written during execution. These blank spaces are unacceptable to most companies and the FDA. The concern is that after execution someone may write in additional information for whatever reason. That is an unacceptable possibility and so there needs to be instruction to eliminate these possibilities.

"Blank data entry spaces and blank COMMENT lines are to be lined through with diagonal lines as needed to cover the blank spaces which will be initialed and dated by the person reviewing the document."



In this case there were no Comments and all lines were marked through to prevent additions at a later date.

E. On occasion you will need to add a page; the page may be a copy of a protocol page to record additional data or a data sheet from a recording instrument. Again the protocol must provide instruction to the executioner.

"Additional pages and or data sheets incorporated into the body of the protocol during execution shall be numbered the same as the proceeding page with the addition of an "alpha" character."

If you're doing the execution and need to add a copy of page 36 it should be numbered 36A with your initials and the date of addition. Treat an inserted recorder page in the same manner. This added page is then inserted into the protocol following the original page (36A comes after 36). If page 36A is a copy of page 36 then it should be stamped in the same manner as page 36 with "COPY"; attached charts are not stamped in this manner.

Once inserted the page number (36A) is initial and dated by the person inserting the page and a note is made in the COMMENTS section of the original page 36 that page 36A has been added.

9. DOCUMENTATION

This is the first section, which actually receives execution. The Documentation Section varies some from facility to facility but usually contains the following sections:

Purchase Specification
Manuals
P&ID's
Materials of Construction Certifications
Welding Certifications
Standard Operating Procedures

See Attachments C-1 through C-9 for samples of each of these pages.

Each section within this portion of the protocol is generally a separate page with instructions for completion at the top.

The following "page" provides some indication of the content of a page as well as critical information relative to components on the page. Review Sections C., D., and E. above to see why and how they fit onto this and all other executable pages.

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In the sections below record the identification of each document and its location. Provide identifying number for each document			
Document #	Document Title	Location	Initial / Date
DWG# 123	Bottle Washer P&ID	Engineering Files	

COMMENTS: _____
_____
_____
_____

Executed By: _____ Date: _____

Reviewed By: _____ Date: _____

Document Number: This is the number assigned by the pharmaceutical facility to the document, not the protocol number.

Document Title: This is the title of the document as written on the document. "ABC Depyrogentation Oven, Model 1410 Operating Manual", "P&ID for WFI System", "Standard Operating Procedure WFI –1415. Operations of Water for Injection System, Bldg. 310", etc.

Location: This is the location of the original or a copy labeled COPY. It is generally best to give Maintenance and Engineering copies and file the original with the validation files for the system. However, wherever the original is found that is the location to be entered.

NOTE: **It is imperative that these validation files are kept up to date. For example a review of the piping in a system which results in "redlines" on the P&ID drawing for that system should end up in the validation files.**

Initials/Date: The initials of the individual executing the protocol and the date on which the location of this specific document was verified.

COMMENTS: This section is available for notes indicating:

Problems
Failure of some portion of the execution
Instructions to refer to additional data in the protocol or elsewhere.
Note that Page 36A has been added
Clarification of some data recorded on this page
Explanation as to why some portion of the requested testing was not performed

EXECUTED BY: Signature of person actually doing the execution of this page.

REVIEWED BY: Signature of person reviewing the completed protocol, not the same person as EXECUTED BY.

Each facility will have specific documents considered important to the validation effort. Those shown are samples and can be adjusted to match the needs and desires of the facility.

NOTE: In several places "Critical", "Non-Critical", "Reference", etc. are used in reference to documents, utilities and instruments. The following generally accepted definitions will help.

EXAMPLE: We have a pharmaceutical reactor producing the final chemical drug material. This vessel is heated with a steam jacket and the overhead vapors are cooled in a condenser with the condensate going to waste. There are the following instruments on

the system:
Steam Supply Pressure to jacket, psig.
Cooling Water Pressure to condenser, psig
Reactor Contents Temperature, ºF

Instruments are classified as follows:

Reactor Contents Temperature: CRITICAL: Has a direct impact on quality, efficacy or purity. Operations will make adjustments affecting the product based on this reading.

Steam Pressure Supply to jacket: NON-CRITICAL: Provides an indication of operability of the system but does not directly impact the product since the operator makes adjustments based on vessel temperature. Does provide an indication about whether or not the batch should be started.

Cooling Water Pressure to condenser: REFERENCE: Is not critical to the operation, may indicate a potential for air pollution but failure of the condenser does not impact product since the condensate goes to waste.

10. TEST EQUIPMENT

There is generally a limited amount of test equipment used in an IQ. The following covers most of what might be used:

Voltmeter	Used to verify that the electrical utility(s) connected to the equipment meet requirements.
Pressure Gage	Used to verify proper pressure for air, nitrogen, water or other fluids essential to proper equipment operation.
Temperature Probe	Verification of temperature of water, heating or cooling fluids or air supplied to the equipment.
Rules, Micrometers other dimension taking devices	Verification of equipment mounting position, position relative to other equipment, internal adjustment dimensions, etc.
Level	Used to verify equipment is installed in a level manner as required by the vendor's documentation and P&ID's.

All of the above should have either an NIST traceability certificate (rules and other items which cannot be calibrated) or a calibration sticker.

See Attachment D for contents of this listing.

11. VISUAL INSPECTION

This is our first view of the equipment as installed. The intent is to verify that the correct machine is installed, that installation matches design, that installation matches equipment manufacturer's recommendation and that the installation is complete. Details vary widely depending on the equipment, Attachment E provides some guidelines.

12. EQUIPMENT COMPONENTS

Finally we look at the machine.
Significant variation exists between companies as to the content, intent and execution of this section. Attachments F-1 through F-5 provide guidance.

The basic guideline here is that we want information to verify that the machine is complete. All motors are installed, all components affecting operation are installed and all utilities are connected.

Information recorded should be sufficient to identify the component without getting into too much detail.

For example a motor can be purchased as replacement for a machine motor with the following information:

Motor horsepower	5 Hp
Operating voltage	480 v / 60 Hz / 3Ø
Motor frame	NEMA 54
Insulation grade	F
Motor speed	1800 rpm

Additional information complicates the protocol without adding significant information.

All critical components should be detailed. For example with the Bottle Washer from before we probably want to record details on:

Indexing motor which turns the bottle rack
Bottle rotator drive system
Water pump used to provide washer water pressure
Air heater used for heating sir for drying
Inlet conveyor
Outlet conveyor
Exhaust fan pulling air and moisture away from washer
Control valves on water and air
Pneumatic or hydraulic cylinders
Wash water needles (inserted into bottle for washing water flow)
Built in computer components (EPROM's)

We don't generally record items similar to the following, which might be on this machine:

Drive belts
Sheet metal parts unless they are specific to a bottle size (change parts)
Fuses and similar electrical components
Motor shaft couplings

There are so many variations on equipment components it is not possible to define all items here. Apply the Critical / Non-Critical guidelines keeping in mind the necessity of maintaining "Quality, Purity, Efficacy". Any item, which could fail or experience a partial failure and effect these guidelines should be considered for inclusion.

13. INSTRUMENTATION

We come back to the Critical and Non-Critical components, the same definitions apply. See Attachment G.

This is an area complete in itself. There should be a company listing of Critical, Non-Critical and Reference Instruments.

List all instruments on each machine, make the Critical determination and proceed for there.

14. UTILITY VERIFICATION

Utilities also fall under Critical and Non-Critical. All utilities should be listed along with their qualities.

Compressed air at 60 psig and 20 degree F dewpoint, 70 degree F, oil free, particulate filtered to 5 microns characterizes the utility completely; flow is generally not given since it will be tested in the utility protocol.
See Attachments H-1 and H-2.

15. EXCEPTION REPORT

Any failure in execution must be resolved. Failures should be recorded as an exception on an Exception Report Form; the form is then passed to someone responsible (Maintenance or Engineering generally) for corrective action.

Once the failure is corrected execution continues.

Failures in an Installation Qualification are rare but do happen. They will generally be mis-connected utilities or the like. All Exceptions must be corrected prior to submittal of the protocol for final approval.

See Attachments I-1 and I-2.

16. SUMMARY REPORT / FINAL APPROVAL PAGE

In an IQ this is simply a statement that the protocol execution is complete and all testing was satisfactory. Frequently this paragraph is combined with the Final Approval page.

> This Installation Qualification Protocol has been completed and the results were reviewed and found acceptable. Any Exceptions found have been reconciled and this system operates and performs properly in accordance with design specifications. This Installation Qualification Protocol has been reviewed and approved by the individuals listed below. List any conclusions or findings in the space provided, or include a summary report as an attachment, if required.

CONCLUSION

Most protocols will contain the pages and sections displayed here; significant variation between companies will alter the order, existence and content of most of these pages.

The intent is to prove satisfactory installation – do whatever is required to accomplish that goal with the fewest number of pages. Good luck!

ATTACHMENT "A"

APPROVAL PAGE

XYZ Pharmaceuticals, Inc.
610 Minuet Lane
Cedar Rapids, MI, 12345

INSTALLATION QUALIFICATION FOR

AUTOCLAVE "F"
Document Number IQ-12

Prepared By: _____ Date: _____
W.N. Weaver PE (Orion Engineering, PLLC, Charlotte, N.C.)

Approvals:

Engineering Manager: _____ Date: _____
John Smith

Validation Manager: _____ Date: _____
Joan Smith

Regulatory Affairs: _____ Date _____
Albert Smith

Production Manager: _____ Date: _____
Jackie Smith

Maintenance Manager: _____ Date: _____
Fred Smith

This document is approved for execution on the date of the last signature.

This page normally is the "cover sheet" as well as the approval page and document identifier (machine, document number, company, location).

ATTACHMENT "B"

EXECUTION APPROVAL PAGE

INSTALLATION QUALIFICATION FOR

AUTOCLAVE "F"

Signatures below indicate that the appropriate individuals have reviewed the executed document and found the results of the execution to be acceptable. This equipment is now ready for testing under the approved Operational Qualification.

Approvals:

Engineering Manager: _____ Date: _____
John Smith

Validation Manager: _____ Date: _____
Joan Smith

Regulatory Affairs: _____ Date _____
Albert Smith

Production Manager: _____ Date: _____
Jackie Smith

Maintenance Manager: _____ Date: _____
Fred Smith