



UM Advanced Topics 2 – Master Record vs Batch Record

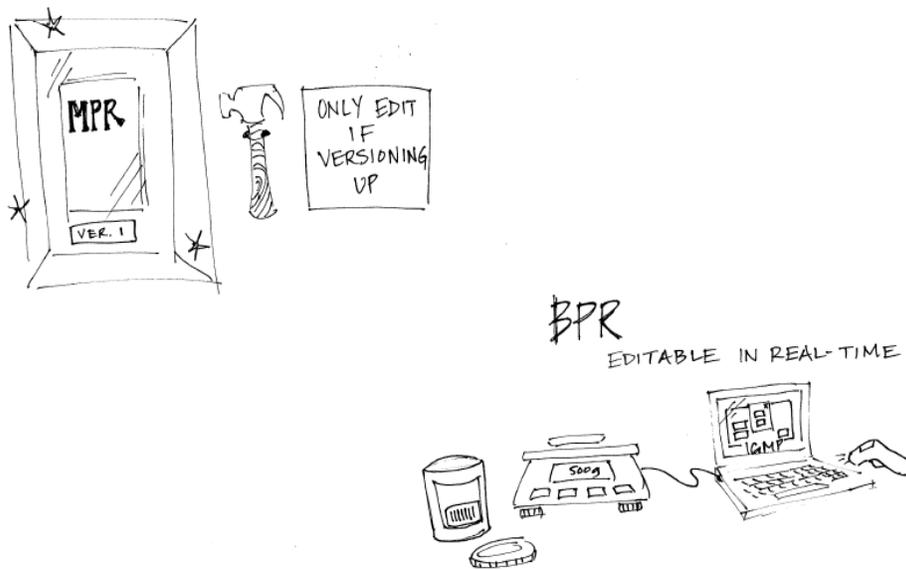
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Introduction

The cornerstone of InstantGMP™ is the electronic Master and Batch Records. If your company has chosen to automate records after historically using picklists and spreadsheets, or if you are new to GMPs, familiarizing yourself with the difference between a Master Production Record (or Master Manufacturing Record) and a Batch Production Record will ease the learning curve of training and data entry.

Think of a Master as the paper on the top floor in a glass case and the batch record as the stamped copy taken to the front lines on the floor.





Master Production Record

A Master Production Record (MPR) is the document on which all departments work together to develop a plan for how a product will be produced. Engineers, Production, drug development/R&D, Operations, Facilities, QA, etc. must weigh in to ensure that the recipe, equipment to be used, required sampling, proper in-process testing and product reconciliation methods are all correctly described in the Master. This MPR document is controlled, meaning that it must be signed by pertinent departments and kept under strict version control.

To review a closed Master Production Record or to edit one In Progress, click on the Master Production Record menu. A screen similar to the one below appears.

Hide	Copy	Ver. #	Scale	Status	Project Title	Product Name	MPR #	MPR Ver. #	Client Name	Formulation Id
<input type="checkbox"/>				Approved	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	267	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				Locked	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	267	2	Haus Bioceuticals	TR112
<input type="checkbox"/>				In Progress	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	268	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				In Progress	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	312	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				Approved	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	308	1	Rite-Aid	06/21
<input type="checkbox"/>				Approved	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	309	1	InstantGMP	06/23
<input type="checkbox"/>				In Progress	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	317	1	Rite-Aid	JF Secret
<input type="checkbox"/>				In Progress	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	308	2	Rite-Aid	06/21

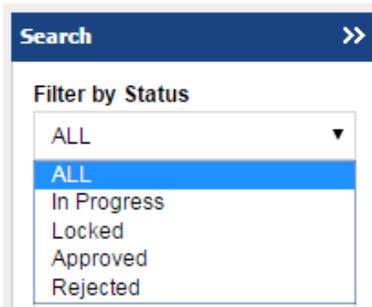
Click on a Product Name hyperlink to open the full MPR. The Cover Page will show Read-Only information. This information will also appear on the Cover Page of a Batch Production Record (BPR) that is generated from this MPR.

Master Production Record	
Project Title	Biotech Example
MPR #	267
MPR Version #	1
Part #	265 Version # 1
Product Name	Recombinant Protein AZ7833- 5 ug/mL
Client	Haus Bioceuticals
Author	p m
Formulation Id	TR112
Product Strength	5 ug/mL
Theoretical Batch Yield	550.000000
Batch Size	500.000000
Batch Unit	g
Primary Container	
Amount / Primary Container	0.00
Amount Unit	
# of Containers	0
Autopopulate BOM QTY on Mfg Instructions	<input checked="" type="checkbox"/>
Purpose	
Scope	
Description	HTbMprCover01

Read-only identification of the signed-off MPR template to be copied to the BPR as read-only



Each Master Production Record is in one of four statuses:



In-Progress indicates the record is still being edited. Locked indicates at least one Approval signature was confirmed and no further editing is allow. Approved means all required signatures were confirmed and a BPR can be generated from this MPR. Rejected means that one person gave a reason to reject and signed the record. A Rejected MPR cannot be used to generate a BPR, but it can be copied to create a new MPR.

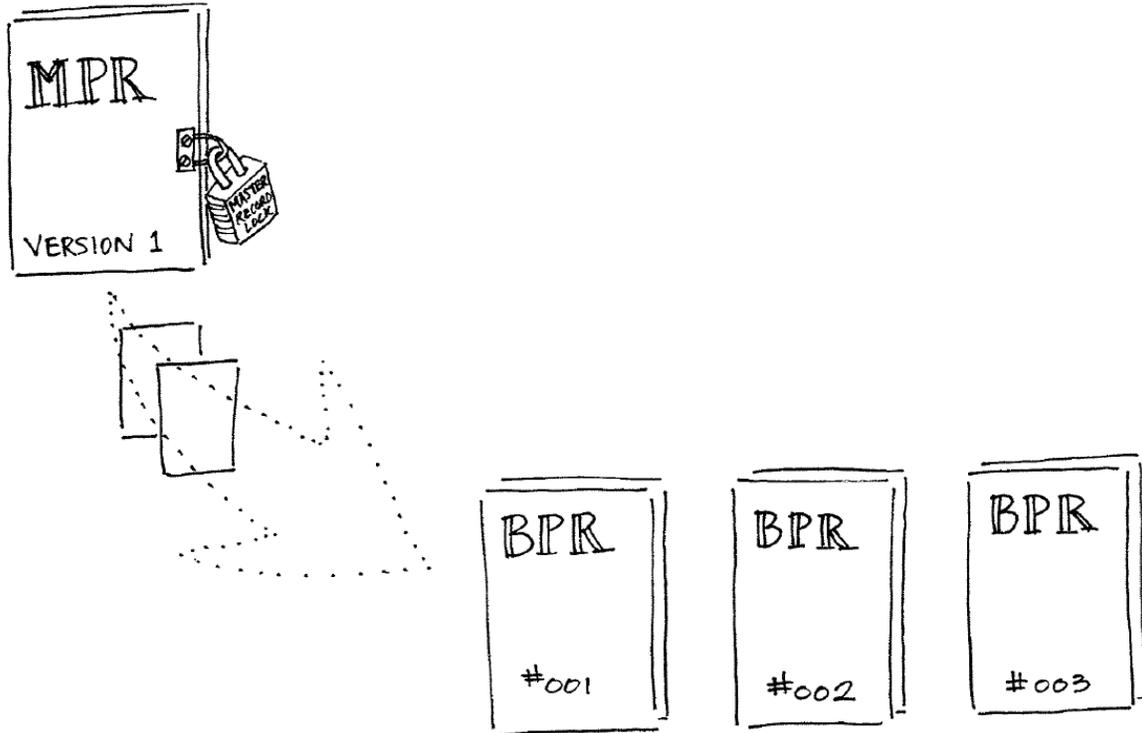
A screenshot of the "Master Production Record" interface. At the top, it displays metadata: "Project Title Biotech Example MPR # 267 MPR Version 1 Part # 265 Version # 1 Product Name Recombinant Protein AZ7833- 5 ug/mL". Below this are several tabs: "Cover Page", "Materials", "Equipment", "In Process Tests", "Manufacturing Instructions", and "MPR Approvals". The "MPR Approvals" tab is active, showing a table with columns: "Approve", "Unlock", "Reject", "Approver", "Job Function", "Date Time", "Reason for Unlock", and "Reason for Reject". Two rows of approval data are visible, each with a green checkmark in the "Approve" column. A green arrow points to the "Approver" column header, and a green box contains the text: "Template is locked down by signatures and Batch Records can be created for each run".

Approve	Unlock	Reject	Approver	Job Function	Date Time	Reason for Unlock	Reason for Reject
✓			p m (pm01)	PROJECT MANAGER	06/07/16 11:17 AM		
✓			Quincent Manager (qm01)	QUALITY MANAGER	06/07/16 11:17 AM		

In a typical paper based organization, Quality Assurance Document Control (QADC) stores paper documents under virtual and key. In an organization that used InstantGMP™, the electronic batch records are the primary record and are accessed by authorized users only. Only a few people may have access to Master Records via an electronic system with encrypted passwords or a locked climate-controlled room. QADC makes sure that the right people are signing the documents and that the documents are not altered after being signed.



Masters are the templates from which Batch records are to be copied. Master records are never to be written on nor filled out.



Below is an example of a manufacturing instruction step at the MPR level:



MPR Instructions = Step-by-step instructions for operators including whether the step is controlled (is inventory used? Are performer and/or verifier signatures necessary?)

Project Title: Biotech Example

Step: 30.00

Part #: 266 **Version # 1** DI Water

Inventory: Click if Inventory will be updated at this step

Performer: Click if Performer signature needed for this step

Verifier: Click if Verifier signature needed for this step

Action: Measure out 50.000000 L of DI Water

Stage in clean room.

Target: 50.000000 Min 49.000000 Max 51.000000 Unit L

Range:

Attachment (2MB limit):

Description: iGMP.TMprManufacturingInstructions **CLOSE**

Parameters are set but NO production data is EVER entered into an MPR!

Instructions designed at the MPR (template) level that will be electronically copied to create a numbered batch record (actionable) with fields for operators to record data specific to a single batch production

A Master must be created for **each batch size** of **each formulation** (product recipe and method of production). For example, a new master must be signed off for each of these products:

500 bottles 6 mg/mL Vanilla vape juice

1500 bottles 6 mg/mL Vanilla vape juice

500 bottles 18 mg/mL Vanilla vape juice

1500 bottles 6 mg/mL Vanilla Caramel vape juice

Master Production Record

Product Name	MPR #	MPR Ver. #	Client Name	Formulation Id	Theoretical Batch Yield	Batch Size
Example Childrens Chewable Vitamin Ras- 50 mg- Plastic Lined Drum	298	1	InstantGMP	Scale up example	1,050.000000	1,000.000000
Example Childrens Chewable Vitamin Ras- 50 mg- Plastic Lined Drum	299	1	InstantGMP	Scale up example	2,100.000000	2,000.000000
Example Childrens Chewable Vitamin Ras- 50 mg- Plastic Lined Drum	300	1	InstantGMP	Scale up example	3,100.000000	3,000.000000
Example Childrens Chewable Vitamin Ras- 50 mg- Plastic Lined Drum	326	1	InstantGMP	werreg	3,100.000000	3,000.000000
Its Ibu 100ct 100mg Org Flv Btl- Bottle Hngd Cap 200mL Wht HDPE	315	1	Rite-Aid	IB PM Org 20160628 Test with Auto kept off	1,005.000000	1,000.000000
Its Ibu 100ct 100mg Org Flv Btl- Bottle Hngd Cap 200mL Wht HDPE	316	1	Rite-Aid	IB PM Org 20160628 Test 2 with auto ON=batch Mini=each	1,005.000000	1,000.000000
Example Foley Catheter Sub-Assembly- Plastic Lined Drum	291	1			100.000000	90.000000
Example Foley Catheter Sub-Assembly- Plastic Lined Drum	292	1			100.000000	90.000000
Example Foley Catheter Sub-Assembly- Plastic Lined Drum	293	1			10.000000	100.000000
Example Foley Catheter Tube- Plastic Lined Drum	294	1			100.000000	90.000000
Example Foley Catheter Tube- Plastic Lined Drum	294	2			100.000000	90.000000
Example Foley Catheter Tube- Plastic Lined Drum	295	1			200.000000	180.000000

A new MPR# (not a new version) is assigned to a Master record when a new theoretical yield/batch size has been selected.

Each batch size of each recipe requires its own signed off, uneditable Master record.



Batch Production Records

Batch Production Records are the actionable forms where operators record the weights, mix times, sampling and performer signatures in real-time during production of a single batch. A batch record should be filled out each and every time the process described therein is followed.

Batch Production Records may only be created from Approved Master Production Records. Usually this is done at the request of a production or operations managers. In a paper based operation QADC must assign a batch record number and stamp it on each page. If a change is needed, a new version of the Master must be created and signed off and a new batch record must be created from the new MPR version.

Whereas a Master Production Record is a template, the Batch Production Record must be used to record production and QA actions in real time. The record must be reviewed by production supervisors or managers and then compiled with other paperwork and sent to QA for review and disposition when completed.

The InstantGMP™ electronic batch record allows operators on the floor to simultaneously work on different manufacturing instruction steps from remote work stations. The system automatically compiles the data in real time into one record with legible electronic signatures.

There is no need to search for and compile, make copies of and store in cabinets and scan and save copious amounts of paperwork. Records referenced in the batch record are within electronic logs so operators can cross reference room and equipment cleaning without leaving the room. QA has access to records immediately after production is completed so the batch review, determination and release process is not only easier but can be initiated sooner than in a paper system.

Batch records create traceability between raw materials and equipment used and the finished good that is ultimately sold.

Production Lot Traceability

Production Number

[Vendor lot numbers of materials used in this batch production](#)

Part #	Rec #	Material Name	Material ID	Vendor Lot #	Unit	Use By	Production Number	Batch Number
147	194	1 oz Amber Bottle	BC1OZAB	abc123	ea	11/12/18	1	0148-01-006
146	210	Training Liquid	TLX-12345	5657	mL		1	0148-01-006



Vendor Lot Traceability

Select Material Name: 1 oz Amber Bottle | Select Vendor Lot #: abc123

SEARCH **CLEAR**

Batches where lot abc123 of 1 oz Amber Bottles were used

Part #	Rec #	Material Name	Material ID	Production #	Batch #	Production Date
147	194	1 oz Amber Bottle	BC1OZAB	12345	0201-01-001	11/12/15 12:00 PM
147	194	1 oz Amber Bottle	BC1OZAB	test	0201-01-002	12/11/15 04:24 PM
147	194	1 oz Amber Bottle	BC1OZAB	teste6	0201-01-004	12/15/15 03:59 PM
147	194	1 oz Amber Bottle	BC1OZAB	1	0148-01-006	12/31/15 10:11 AM
147	194	1 oz Amber Bottle	BC1OZAB	teste6	0201-01-004	12/15/15 03:59 PM
147	194	1 oz Amber Bottle	BC1OZAB	teste6	0201-01-004	12/15/15 03:59 PM
147	194	1 oz Amber Bottle	BC1OZAB	0226-01-001	0226-01-001	02/26/16 03:22 PM
147	194	1 oz Amber Bottle	BC1OZAB	0226-01-001	0226-01-001	02/26/16 03:22 PM

Traceability serves as proof of production controls, of a quality product and as reference for any recalls as well as a way to monitor micro-trends and have a basis for evaluating and improving processes.

InstantGMP™ automates the process of creating, versioning and scaling up master records and electronically creates batches from masters in a few clicks of the mouse. The software creates a secure, remote, central workspace and document repository so that all departments can work on and sign off on a Master production record with less meetings and with no waiting for hand delivered intra-office mail.

Master Production Record

Hide	Copy	Ver. ↕	Scale Ⓟ	Status	Project Title	Product Name	MPR #	MPR Ver. #	Client Name	Formulation Id
<input type="checkbox"/>				Approved	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	309	1	InstantGMP	06/23
<input type="checkbox"/>				In Progress	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	317	1	Rite-Aid	JF Secret
<input type="checkbox"/>				In Progress	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	308	2	Rite-Aid	06/21



Creating and Issuing a Batch Production Record

InstantGMP™ creates security for your documents and eliminates the need to make paper copies and check logs for the next batch # to stamp on each page of the Batch Record. The automation means batches are automatically numbered and there is no need to check for smudges in the ink, a missing page or an incorrect batch # stamp.

Batch records can only be created from Approved MPRs. The system will not allow selection of non-approved master records.

Hide	Copy	Ver. #	Scale	Status	Project Title	Product Name	MPR #	MPR Ver. #	Client Name	Formulation Id
<input type="checkbox"/>				Approved	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	267	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				Locked	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	267	2	Haus Bioceuticals	TR112
<input type="checkbox"/>				In Progress	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	268	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				In Progress	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	312	1	Haus Bioceuticals	TR112
<input type="checkbox"/>				Approved	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	308	1	Rite-Aid	06/21
<input type="checkbox"/>				Approved	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	309	1	InstantGMP	06/23

Creating a Batch Production Record is only a few clicks of the mouse. A BPR is generated from the MPR using the “Add New Record” button at the bottom of the Batch Production Record summary screen.

Hide	Status	Issue Date	Production Date	Project Title	Product Name	Theoretical Batch Yield
<input type="checkbox"/>	Reviewed	05/07/16 11:29 AM	05/07/16 11:43 AM	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	550.000000
<input type="checkbox"/>	In-Process	05/07/16 11:46 AM	05/07/16 11:48 AM	Biotech Example	Recombinant Protein AZ7833- 5 ug/mL	550.000000
<input type="checkbox"/>	Added to Inv	05/21/16 02:59 PM	05/21/16 03:14 PM	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	110.000000
<input type="checkbox"/>	Generated			Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	110.000000
<input type="checkbox"/>	In-Process	12/08/15 10:45 AM	12/08/15 10:46 AM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.000000
<input type="checkbox"/>	Reviewed	12/09/15 07:14 AM	12/09/15 07:14 AM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.000000
<input type="checkbox"/>	In-Process	12/09/15 07:22 AM	12/09/15 07:22 AM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.000000
<input type="checkbox"/>	In-Process	12/09/15 08:57 AM	07/12/16 03:39 PM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.100000
<input type="checkbox"/>	In-Process	05/27/16 01:06 PM	07/12/16 03:39 PM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.100000
<input type="checkbox"/>	In-Process	12/09/15 09:12 AM	12/11/15 11:41 AM	CMO Batch Record Review	MetaDerm Psoriasis Cream	1.200000
<input type="checkbox"/>	In-Process	11/11/15 03:56 PM	11/11/15 03:57 PM	Dietary Supplement Example	Chevable Vitamin C Tablet- 500 mg- HDPE White Bottle- 50 Count	10,500.000000
<input type="checkbox"/>	Added to Inv	11/12/15 11:58 AM	11/12/15 12:00 PM	Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	550.000000
<input type="checkbox"/>	In-Process	07/11/16 04:10 PM	07/11/16 04:21 PM	Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	1.000000
<input type="checkbox"/>	Issued	07/11/16 05:29 PM		Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	1.000000
<input type="checkbox"/>	In-Process	12/11/15 04:24 PM	12/11/15 04:24 PM	Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	227.000000
<input type="checkbox"/>	Generated			Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	500.000000
<input type="checkbox"/>	Generated			Dietary Supplement Example	B Complex with Vitamin C- 60mg- 1 oz Amber Bottle- orange flavor	1.000000

After generating the draft BPR, click the Cover Page tab. Note that after choosing Project “Biotech Example,” MPR version 267 version 1 is available but version 2 is not available for copying to an actionable Batch Record since it is waiting on signatures and is in a locked status:



BPR Cover Page

Project Title *	Biotech Example
Product Name *	Select Product Name
MPR #	Select Product Name (MPR #: 267 / MPR Version #: 1) Recombinant Protein AZ7833- 5 ug/mL

After selecting the MPR/version, all of the MPR data is copied into the BPR document:

Batch Production Record

Batch #: 0332-01-001

- Cover Page
- Material
- Equipment
- In Process Testing
- Manufacturing Instructions
- Executed BPR Review

Project Title	Pharmaceutical Example
MPR #	332
MPR Version #	1
Part #	226 / 1
Product Name	Childrens Chewable Vitamin Ras- 50 mg- Plastic Lined Drum
Production	SCALE VIDEO
Batch #	0332-01-001
Manufacturing Date	// 12:00 AM
Client	InstantGMP
Author	Paul Manager (PManager01)
Formulation Id	VIDEO
Product Strength	50 mg
Theoretical Batch Yield	3,100.000000
Batch Size	3,000.000000
Batch Unit	kg
Primary Container	Plastic Lined Drum
Amount/Primary Container	0.00
Amount Unit	
# of Containers	0
Autopopulate BOM Quantity on Mgf Instructions	<input checked="" type="checkbox"/>
Purpose	
Scope	
Description	rest-aid1955932.docx
Issue Date	DBADM DBAdministrator (DBADM) 08/15/16 03:06 PM EDT

HTbBprControl01

UPDATE

PRINT



Batch Production Records have six statuses in InstantGMP™:

Show Status

ALL ▼
 ALL
 Generated
 Issued
 In-Process
 Locked
 Reviewed
 Added to Inv

Generated indicates that the record has been created but is not yet issued. **Issued** means that the record has been issued and is open for data entry. **In-Process** shows that the record has been used to start recording data. **Reviewed** indicates that all required signature were confirmed and **Added to Inventory** means that the amount of product produced was electronically added to inventory.

The document is locked in “Generated” status until the Batch is Issued by QA. Note there is no issue or production date for the generated batch below:

Hide	Status	Issue Date	Production Date	Project Title	Product Name	Theoretical Batch Yield	Batch Size	Batch Unit	MPR #	MPR Ver. #
<input type="checkbox"/>	Reviewed	06/07/16 11:29 AM	06/07/16 11:43 AM	Biotech Example	Recombinant Protein AZ7933- 5 ug/mL	550.000000	500.000000	g	267	1
<input type="checkbox"/>	In-Process	06/07/16 11:46 AM	06/07/16 11:48 AM	Biotech Example	Recombinant Protein AZ7933- 5 ug/mL	550.000000	500.000000	g	267	1
<input type="checkbox"/>	Added to Inv	06/21/16 02:59 PM	06/21/16 03:14 PM	Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	110.000000	100.000000	g	308	1
<input type="checkbox"/>	Generated			Bottled starch	Bottled Starch- 100%- HDPE White Bottle- optional	110.000000	100.000000	g	308	1

Note that the steps on the Manufacturing Instructions tab are not editable and no not yet have color-coded progress icons:

Batch Production Record						
Batch #: 0308-01-002						
Cover Page	Material	Equipment	In Process Testing	Manufacturing Instructions	Executed BPR Review	
Status	Step	Part #	Material	Version #	Action	
	10.00	0		0	Very room has been cleaned	
	20.00	0		0	Uncover equipment	
	30.00	0		0	stage starch	
	40.00	0		0	stage bottles	
	50.00	268	Starch	1	Measure out 11100.000000 g of Starch Pour starch into hopper	
	60.00	269	Plastic Bottle 100 count w/hinged lid HDPE	1	Measure out 110.000000 ea of Plastic Bottle 100 count w/hinged lid HDPE place bottles on fill line	
	70.00	0		0	Fill bottles with target starch	
	80.00	0		0	Perform in process test 1 for odor	
	90.00	0		0	Perform final filled bottle count and record	

The software prevents batch issuance if materials necessary for production are not available or not approved. Your team will never be staging for a batch and find that some materials are still in



quarantine. Error messages will alert QA of any materials which are still in Quarantine or if there is not enough to make the batch.

The Material: Training Liquid has been Requisitioned but not received

In the example below, the batch has been Issued. Note that the edit icons are available to operators so they can add results:

Batch Production Record						
Batch #: 0331-01-001						
Cover Page	Material	Equipment	In Process Testing	Manufacturing Instructions	Executed BPR Review	
Status	Step	Part #	Material	Version #	Action	Result
	10.00	147	1 oz Amber Bottle	2	Measure out 14.761904 ea of 1 oz Amber Bottle Stage in production room	
	20.00	181	Chewable Vitamin C Tablet	1	Measure out 1623.809523 ea of Chewable Vitamin C Tablet	
	25.00	276	Sucrose	1	Measure out 5.000000 g of Sucrose record scale CAL date	
	30.00	0		0	Put 10 tablets in each bottle	
	40.00	0		0	Check appearance of bottles	
	50.00	0		0	Select v-blender for mixing. Add all ingredients after screening each. Mix for 20 minutes	