

Understanding Roles, Access, Signature Permissions and Session Patterns in InstantGMP™
3.002.008

Glossary

ADM	The Administrator is a hybrid role/named personnel in the system with limited permissions
Role	Predetermined set of access and signature permissions assigned to a user
Access	A role’s ability to get to screens, add and edit data
AR	Administrator Rights
Personnel	In general, the users of the system; specifically refers to a single user defined by their unique userID
RW:	Read/Write permissions or “ALL” permissions
Signature Permissions	Allowance of roles or by specific UserID to sign for edits or record approvals
Session	The occurrence of being logged into the InstantGMP instance on a certain computer with a certain UserID/credentials.

Granting Rights to the “Set Up” Screens via “Is AR” Checkbox (administration rights)

Note: set up screens are generally not assigned access by role but rather by the “AR rights” checkbox on the personnel screen. Inventory manager has role-based access to setup screens.

The “Is Administrator” setting on the personnel screen grants users RW permissions on the Set Up screens.

This set of permissions is generally not role based, however most roles can see the equipment type set up screen and the Inventory Manager role has access to all set up screens.

Roles:

*Note: The “ADM” is not a role. The ADM (name) is a personnel UserID intended for temporary use and is granted access to Set Up screens via “AR rights” permissions for entry of the first personnel into the system if a Training Specialist (DBADM) did not have required information to do so on customer’s behalf. The ADM does **not have signature rights** and prolonged use of the ADM userID is **not FDA compliant as it is not associated with a single named user.***

Role code	Role Name	(possible company titles) General description/permissions	Is Management	Has Permissions to Set Up screens without AR rights assigned
PM	Project Manager	(Project Manager, Operations Lead, Production Manager)	Y	Equipment type only

		Can create documents and see most screens. Cannot change status of material, issue a batch or sign off on deviations.		
QM	Quality Manager	(Quality Manager, QADC, QA Release, etc.) Only role that can change status of material, issue a batch, lock down specifications or sign off on deviations. Cannot begin a Master record nor edit the BOM. Cannot add secondary personnel roles to a project.	Y	Equipment type only
PS	Production Supervisor	(Production Supervisor, Floor Manager) Can sign for specifications. Generally, follows what a PM can do except cannot make projects.	N	Equipment type only
INV	Inventory Manager	For use with a system only utilizing Inventory, (No MPRs or BPRs) (Warehouse Manager, Material Manager, etc.) Can access setup screens. Has PM and QM permissions. Cannot see reports for vendor lot #/ or Batch # traceability.	Y	Y
OP	Operator	(Operator, production employee, etc.) Can sign for material receipt, material use, location change, manufacturing instruction steps, room and equipment log performer, and can see reports. Cannot see master records. Cannot generate nor issue batches.	N	Equipment type only
QO	Quality Operator	(QADC, QC, QA operators) Similar to Operator role except can see the audit trail.	N	Equipment type only
IO	Inventory Operator	(warehouse operator) Similar to Operator role except can requisition materials. Cannot see MPRs or BPRs, nor traceability reports.	N	Equipment type only
GU	Guest	Can navigate screens except for those with tabs (projects, MPR,	N	N

		BPR) and has no signature rights.		
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Roles and Actions Table

The table below defines the Actions via signature that are assigned to each of the default roles in the application.

Role	BPR Performer	BPR QA Issuer	BPR Verifier	Equipment Log Updater	Equipment Log Reviewer	Inventory Status Updater	Inventory Use Updater	Material Receiver	Material Spec PM/PS Approver	Material Spec QA Approver	Requisition Requestor	Room Log Updater	Room Log Reviewer	Deviation Approver
DBAD M	X	X	X	X	X	X	X	X	X	X	X	X	X	X
PM	X		X	X	X		X	X	X		X	X	X	
QM	X	X	X		X	X	X	X		X	X		X	X
PS	X		X	X	X		X	X	X		X	X	X	
INV						X	X	X	X	X	X			
OP	X		X	X			X	X				X		
GU														
IO							X	X			X			
QO	X		X	X	X		X	X			X	X	X	

E-Signature Table: Action Buttons and Labels

This table describes the button names and signature labels associated with each Action.

Activity	Button Name	Pre-Signature Label	Post-Signature Label
Bin Location Change	Sign	Signature Required	Approved By
BPR Performer	Sign	Performer Required	Performed by
BPR Verifier	Sign	Verifier Required	Verified by
Equipment Log Updater	Sign	Signature Required	Signed by/Operator
Equipment Log Reviewer	Sign	Review Required	Reviewed by/Reviewer
Inventory Use Updater	Sign	Signature Required	Approved by
Material Receiver	Sign	Receiver Required	Received by
Requisition Requestor	Sign	Signature Required	Ordered by
Room Log Updater	Sign	Signature Required	Signed by/ Operator
Room Log Reviewer	Sign	Review Required	Reviewed by/ Reviewer
Material Spec Approver	Approve	PM/PS Signature Required	Approved by
Material Spec QA Approver	Approve	QM Signature Required	Approved by
MPR Approver	Sign	Signature Required	Approve
MPR Reject	Sign	Signature Required	Reject
Inventory Status Updater	Disposition	Status	Dispositioned by
BPR QA Issuer	Issue	QA Signature Required	Signed by
Deviation Review	Review	QA Signature Required	Signed by
BPR Approver	Sign	Signature	Approver

Note:** the above tables pertain to those “Actions” which are defined as such by the software code. There are additional activities that are **controlled by rules** as well as those that **do not require signature** (and combinations thereof) that are not considered “Actions” which do not appear on the chart, such as the creation of a material. The details of these permissions are in an extensive table which represents the security clearances for each role on each screen. Key aspects of this chart can be seen in a **synopsis of the Object Access Chart below.

Activity/Role Chart (Key Rule-Controlled and/or non-Signed)

Note: This chart is a synopsis of the extended security chart and should answer the most commonly asked user questions. This information is complementary to the signature Actions chart as it includes those activities that are not considered “Actions” and in general do not require signatures to complete.

Activity	GU	INV	IO	OP	PM	PS	QM	QO
View equipment type (set up)	X	X		X	X	X	X	X
Add materials to system		X			X			
View materials	X	X	X	X	X	X	X	
Create Specifications (not sign)		X			X	X	X	
View specifications	X	X			X	X	X	
Add attachments for materials							X	
Use Materials		X	X	X	X	X	X	X
Change Material Location		X	X	X	X	X	X	X
Split Lot		X	X	X	X	X	X	X
Save Project title, products, client, personnel					X			
See Projects	X				X		X	
Create MPRs					X		X	
Edit MPR BOM					X			
Copy BOM from other MPR					X		X	
Edit MPR Equipment					X		X	

Copy MPR equipment form another MPR					X		X	
Edit In-Process tests					X		X	
Copy in-Process tests from another MPR					X		X	
Edit manufacturing Instructions					X		X	
Copy manufacturing instructions from another MPR					X		X	
See MPRs list, cover pages, approval pages	X				X	X	X	
See MPRs – all tabs	X				X		X	
Sign Review/Rejection of MPR (if assigned signatory responsibility by User ID)					X	X	X	
Create BPRs					X	X	X	
See BPRs				X	X	X	X	X
Execute BPRs				X	X	X	X	X
Sign “Executed BPR Review” (if assigned signatory responsibility by User ID)				X	X	X	X	X
Edit BPR cover page attachment					X	X	X	
Add Batch to Inventory				X	X	X	X	
Run reports		X	X	X	X	X	X	X
Audit Trail access	X	X			X	X	X	X

Primary Role

Primary roles (Default Job Function) are assigned at the Personnel screen and will remain set as the first identified primary role (changing this role after the fact will not change projects.)

Personnel

First Name *

Last Name *

Phone

Fax

Address

City

State

PO Box

Zip

Email

Country

User

Default Job Function *

Password *

Administrator

Disabled

Signature Badge

Start Date

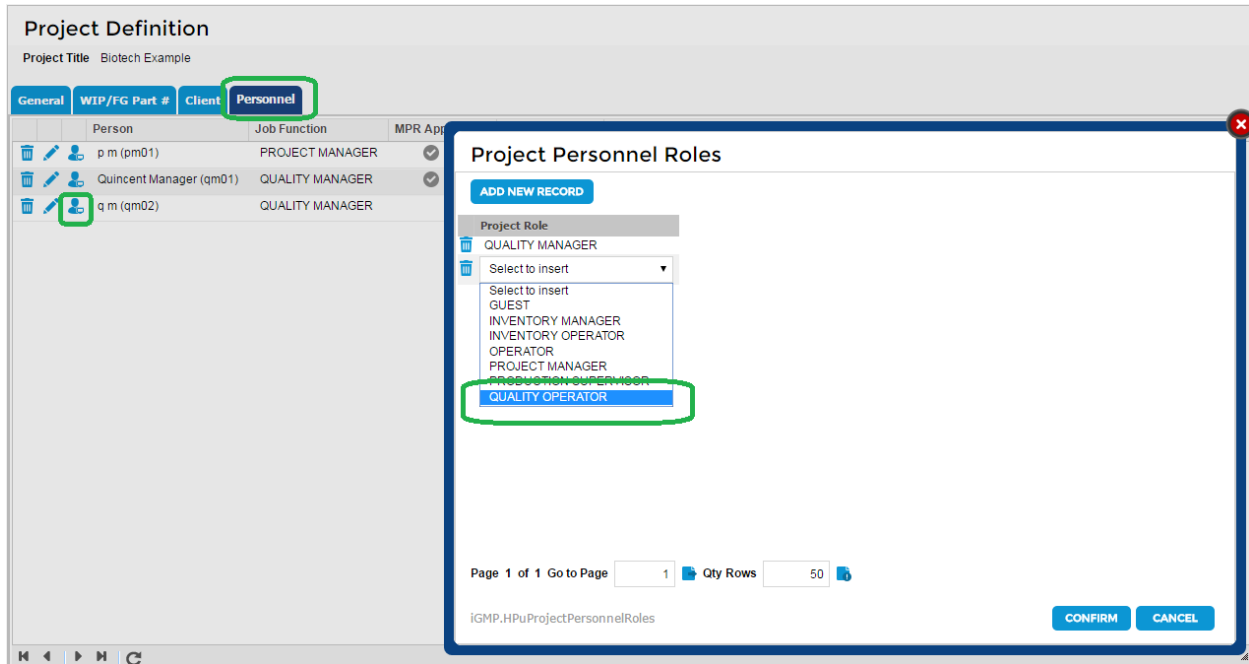
End Date

Code

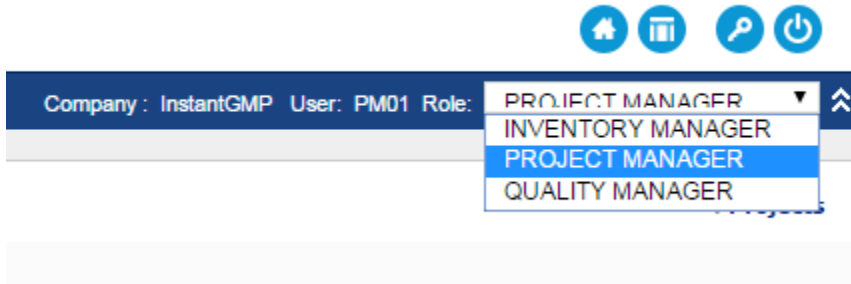
iGMP.TPersonnel

Secondary Roles

Secondary roles may be assigned at the project level



Within a logon session, users may toggle to secondary roles using the drop down in the upper right hand corner of the system.



Signing Rules and Sessions

Your InstantGMP™ support specialist can toggle the signature rules for specific applications or customers. GMPs require that different signatories sign for performer and verifier of the same step. For manufacturers using InstantGMP™ to manufacture products not yet regulated by the FDA, this can be toggled to allow for the same UserID to sign for performer and verifier of the same task such as log entries and manufacturing instruction steps.

A session represents the unique login to a particular InstantGMP™ instance by a certain UserID. The time spent logged in by that UserID in the program is the session. If a User is logged in and passes the mouse to another User, certain actions can be done on the session already open and some actions require that the User with the role required to sign for the action must login and create a new session. This is a combination of security and GMPs.

Session/signature rules

Screen	Role/UserID Specific	Need to be Session initiator to sign?
Specifications	Role; PM/PS, QM	Yes
Requisitions	N/A	No
Material Receipt	N/A	No
Inventory Status Change	Role; QM, INV	Yes
Inventory Use	N/A	No
Inventory Location Change	N/A	No
Room Log performer	N/A; QM cannot sign	Yes
Room Log verifier	N/A	No
Equipment Log performer	N/A; QM cannot sign	Yes
Equipment Log verifier	N/A	No
MPR signature	UserID	No
BPR signature	UserID	No

For further information about Roles and permissions, refer to the User Manual or contact your InstantGMP™ Support Specialist. You may also book consulting time to discuss how to use the included roles in InstantGMP™ to their full potential with your team's unique circumstances.

For customization to roles please contact sales director Robert Pochadt rpochadt@instantGMP.com or Pharma sales rfitzgerald@instantgmp.com to begin the process of creating additional roles with the design team.