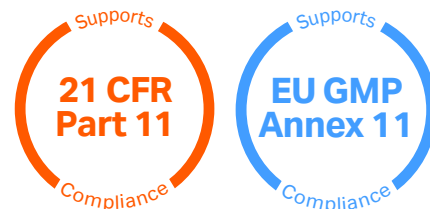


Amersham

ImageQuant 800 GxP

IMAGING SYSTEMS, SOFTWARE, AND ACCESSORIES



ImageQuant™ 800 systems are a new generation of highly sensitive and robust charge-coupled device (CCD) imagers for capturing high-quality images in life science applications (Fig 1). This new range of systems is ideal for chemiluminescence, fluorescence (including IR), and colorimetric imaging — including optical density measurements of a wide variety of samples, like gels, membrane blots, multiwell plates, and petri dishes.

ImageQuant 800 with GxP is specifically designed to meet the increasing requirements of good practice GxP frameworks and regulations like FDA 21 CFR part 11 and EU GMP Annex 11 — where data traceability, accountability, and integrity are critical. Here we describe how you can use the ImageQuant 800 GxP system in a controlled environment like a biopharmaceutical QC lab.

Key benefits of ImageQuant 800 GxP

- **Windows™ based user login:** Log on to the imager with Windows authentication to ensure a single continuous period of access that is secure and controlled.
- **User groups for controlled system access:** Assign user groups to only grant access to relevant software functions.
- **Electronic records and event logs:** Retrieve time-stamped audit trails and image files with relevant capture information that is embedded and protected.
- **Digital handshake to ensure image data integrity:** Check image authenticity automatically with ImageQuant TL (IQTL) GxP analysis software before analysis.
- **Data traceability:** Enter your electronic lab notebook reference number to ensure electronic data traceability back to experimental steps before imaging.
- **Full documentation and validation support:** Sign up for Cytiva's regulatory support to access full development documentation, change control notifications, and external assessment reports.



Fig 1. Amersham ImageQuant 800 CCD imaging system

Introduction to GxP

Quality guidelines and regulations help ensure that pharmaceutical products are safe for their intended use, and that the manufacturing, control, storage, and distribution processes adhere to documented quality processes. GxP is an abbreviation for good practice — “x” can stand for manufacturing or lab. GxP regulations describe requirements and guidelines on how you can use standard protocols for safe electronic record keeping.

GxP regulations cover:

- **Traceability:** The ability to reconstruct the development history of a drug or medical device.
- **Accountability:** The ability to verify who has contributed what to the development and when.
- **Data integrity:** The reliability of data generated by the system, including:
 - Identifying data generated by the system
 - Defining data integrity requirements during the data life cycle
 - Identifying risks and mitigation strategies

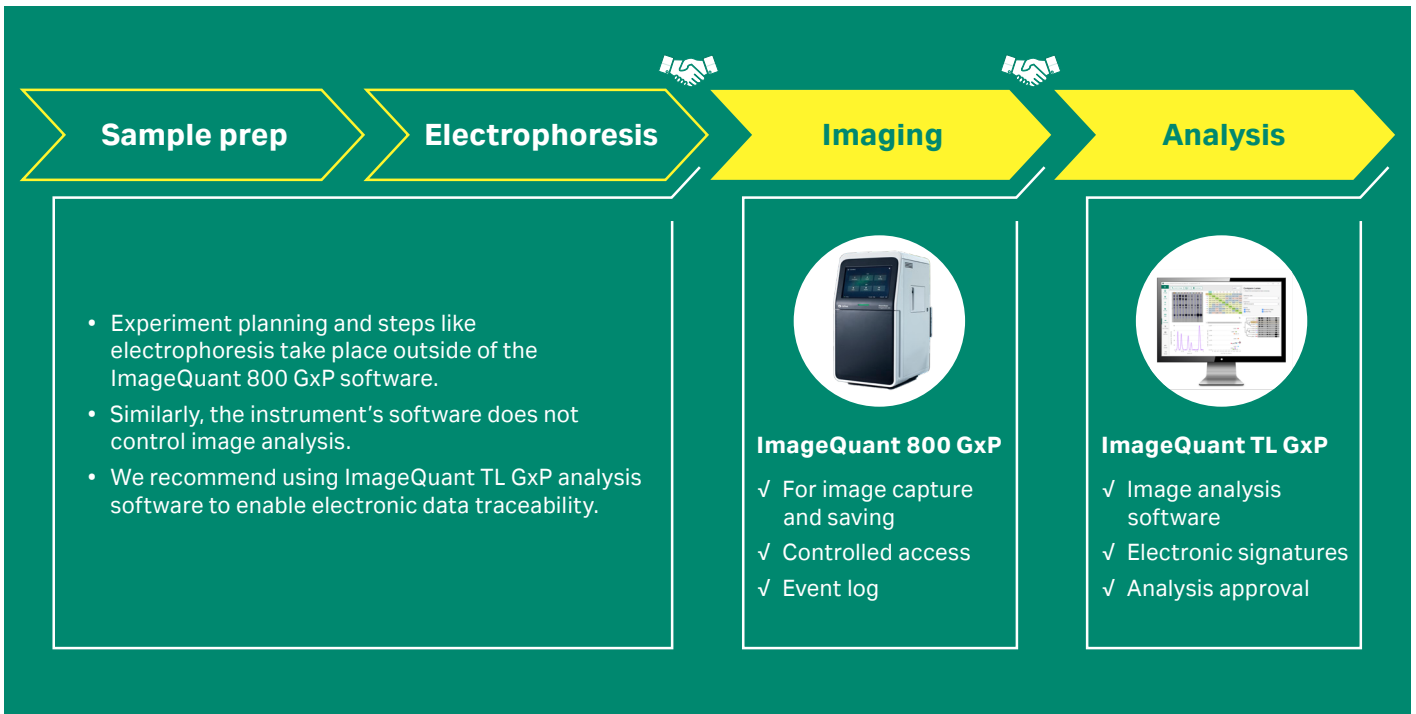


Fig 2. Typical imaging workflow.

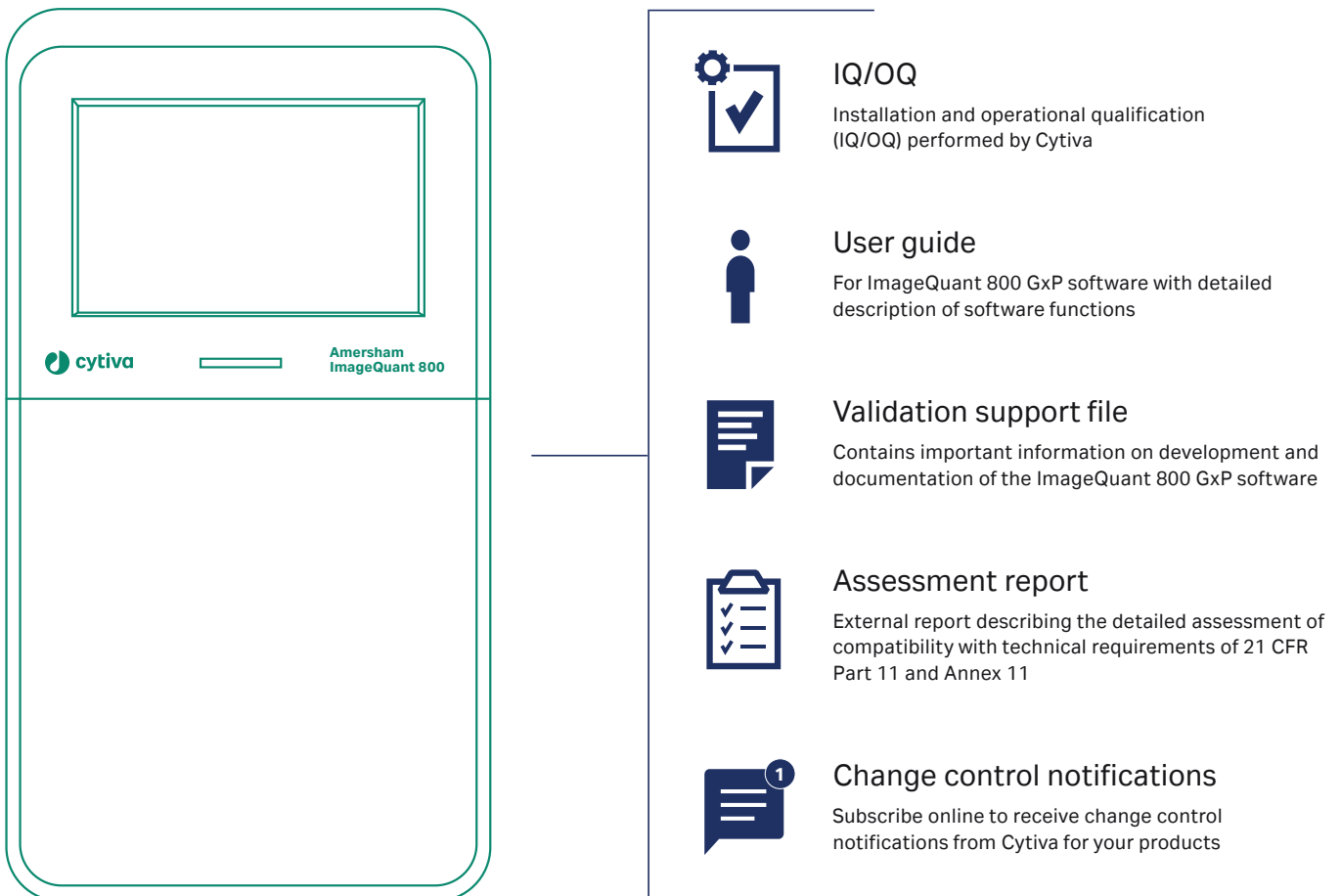


Fig 3. Full regulatory and validation support with Amersham ImageQuant GxP.

Scope of Amersham ImageQuant 800 GxP

You can use ImageQuant 800 GxP software products in a GxP-regulated environment to maintain electronic records. This software includes functionality to enable compliance with FDA 21 CFR Part 11¹ and EU GMP Annex 1².

We designed ImageQuant 800 GxP for use as a closed system, according to the definition:

“Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.”

Based on this definition, it's the users' responsibility to ensure that only relevant employees with controlled access operate the system.

Standard operating procedures in regulated QC labs generally contain multiple steps that include many smaller instruments and consumables before the imaging and analysis stage. We outlined these that are typical before image acquisition (Fig 2).

Cytiva's scope for GxP compliance is restricted to the control software of the ImageQuant 800 imaging system, followed by analysis in the ImageQuant TL GxP analysis software. However, you can enter the sample ID, electronic lab reference number, or equivalent on the imager to ensure data traceability to experimental steps before imaging.

Complete GxP offering for regulated environments

Our quality management system is certified by ISO 9001 standards. The ImageQuant 800 GxP offering includes a suite of regulatory support documentation and services that enable you to meet industry requirements with confidence. (Fig 3.)

[Register with Cytiva online](#) to access relevant regulatory documentation and subscribe to change control notifications.

Key features that support users in a regulated environment

System flexibility

The Amersham ImageQuant 800 system comes with an external Windows 10 IoT Enterprise edition computer recommended by Microsoft for use in industrial settings. The external computer also allows users to update software and change computers as needed.

Electronic records

The TIF image file is the primary electronic record³ containing all information relevant to image capture. You can view the information in the imager or IQTL GxP analysis software. The system automatically stores data including username, date, time, imaging conditions, and more (Fig 4).

Audit trail support

The event log generated by the ImageQuant 800 GxP is a history of events you can use for an audit. For example, you can crosscheck this information to confirm your image file data is accurate (Fig 5). The event log can be viewed on the control software and exported as PDF or printed if needed.

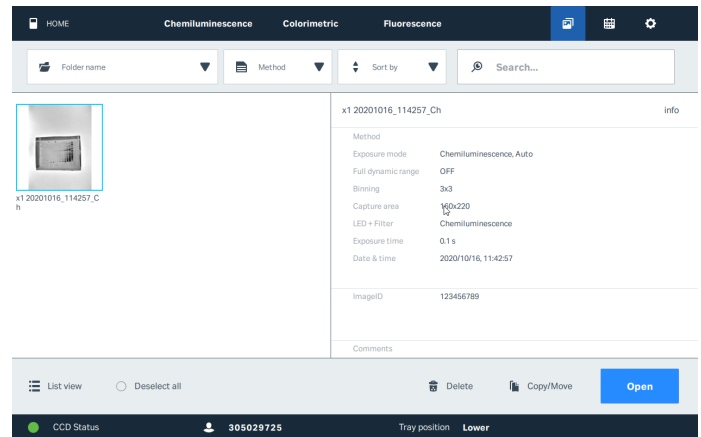


Fig 4. Viewing all image information in the ImageQuant 800 GxP software.

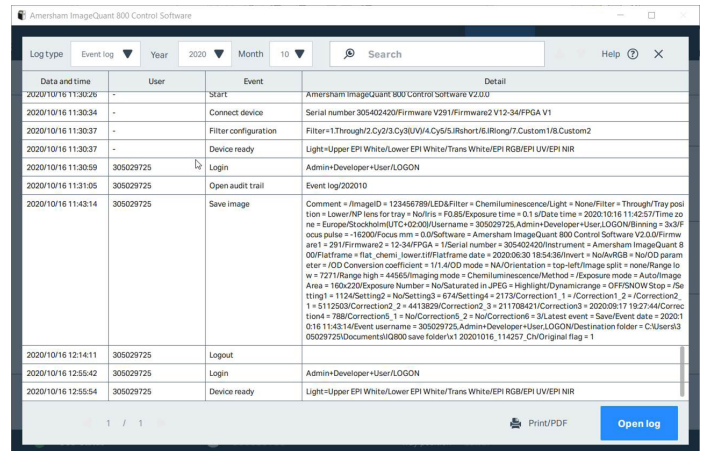


Fig 5. Event log viewer in the Amersham ImageQuant 800 GxP software.

Authentication and Identification

The system uniquely identifies users with two components, their username and password. The FDA 21 CFR part 11 regulations recommend that users have a single continuous period of controlled system access.

• User login using Windows authentication

The login for the Amersham ImageQuant 800 GxP system is linked to Windows authentication. Once a user has logged on using their username and password, the same credentials are used to log on to the ImageQuant 800 GxP control software. This ensures a secure and controlled login and access to the imager. This also allows the ImageQuant 800 GxP control software to directly follow any user login rules set by your organization, such as password expiration policies.

• Dynamic lock function

If the user needs to step away from the imager, the Dynamic lock function can be used. Dynamic lock enables the imager to continue imaging while remaining locked until the user logs back on with their username and password. This feature helps to control access during unattended periods of time and further ensures a single continuous period of system access by the user.

User roles and access within the GxP software

The ImageQuant 800 GxP software allows the admin user to assign roles to other users based on their function in the lab. This ensures that only relevant personnel have access to certain functions. You can also assign multiple roles to a single user if needed.

Role	Manage users	Create methods	Use methods	Capture image without method	Basic image editing
Admin	✓	×	×	✓	✓
Developer	×	✓	✓	✓	✓
User	×	×	✓	✓	×

Applications

Linear optical density measurements using ImageQuant 800

In any biopharmaceutical process, it is critical to measure two parameters of an intermediate or final product:

1. Amount of biopharmaceutical, e.g., mAb (concentration usually compared to a reference sample)
2. Purity, i.e., quantity of target substance compared to impurities in the same sample

You can measure both of these parameters using ImageQuant 800. The imager has a unique factory-calibrated densitometry mode for Coomassie™ stained gels that automatically converts intensity data to optical density (OD) values. The amount of light transmitted through a material decreases exponentially as it travels through the material. The negative logarithm of the ratio I/I_0 , i.e., the OD, is directly proportional to the concentration of the absorbing stain (Fig 6).

By measuring the optical density with the ImageQuant 800, you can accurately quantify the amount of stained proteins. OD is directly proportional to the concentration of the absorbing stain and is linear over a wide dynamic range. The highly sensitive optics and excellent dynamic range of ImageQuant 800 allows users to accurately quantify low levels of impurities.

Additionally, confirmation of identity of the final product or intermediate is based on molecular weight and similarity of lane profiles to reference samples. You can do this manually or using analysis software like IQTL.

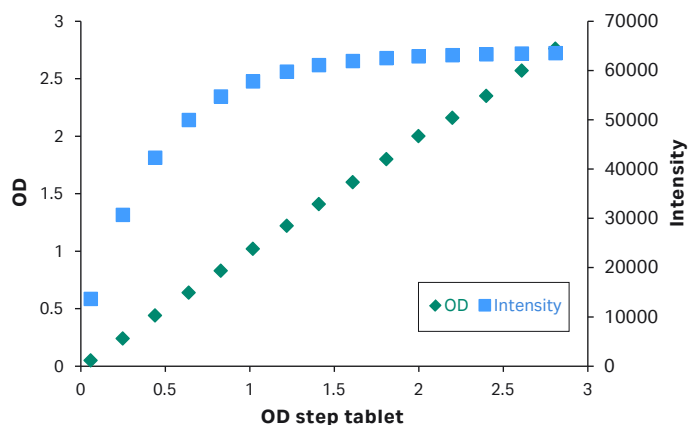


Fig 6. Intensity versus sample OD is a nonlinear function, while OD shows linear response over a wide dynamic range — making it ideal for accurately measuring protein concentration and purity.

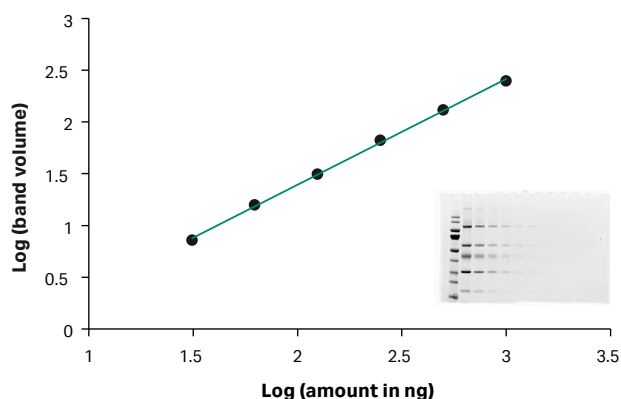


Fig 7. We analyzed an optical density (OD) image of a Coomassie stained gel with a dilution series with ITQL. The band volumes exhibited excellent linearity across a wide dynamic range (slope $k = 1.0$).

Effortlessly resolving target proteins from other proteins of similar molecular weight

To visualize proteins, treat a gel with a total protein stain after performing 1D or 2D electrophoresis. The most commonly used stain is Coomassie blue. The high-resolution camera in the ImageQuant 800 system can resolve even the most closely spaced bands, allowing accurate quantitation for critical applications (Fig 8).

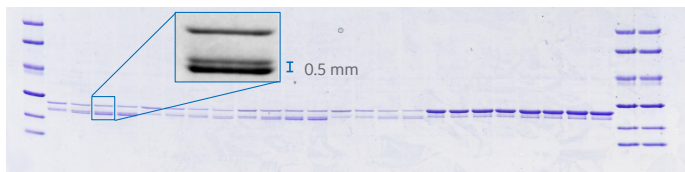


Fig 8. Colorimetric imaging with Amersham ImageQuant 800 imager results in high-resolution images for the most demanding applications. The zoom in of the Coomassie stained gels shows that it is possible to resolve bands on a gel which are only 0.5 mm apart. For research on self-cleaving tags, being able to differentiate these bands is critical.

Qualification services: Equipment life cycle management

Cytiva offers qualification services to support your equipment throughout its entire life cycle. Our tests and protocols are developed and approved by qualification experts and performed by trained and certified service engineers. Our approach is in alignment with GAMP5, ICH Q8-10, and ASTM E2500 — our qualification activities and documentation focus on what is critical for end-product quality, and are scaled according to risk, complexity, and novelty. Our qualification offerings include installation and operational qualification (IQ/OQ), requalification (RQ), and change control protocols (CCP).

References

1. Title 21—Food and Drugs; Chapter I—Food and Drug Administration Department of Health and Human Services; Subchapter A—General; Part 11—Electronic Records; Electronic Signatures
2. EudraLex, The Rules Governing Medicinal Products in the European Union, Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Annex 11: Computerized Systems
3. Title 21—Food and Drugs; Chapter I—Food and Drug Administration Department of Health and Human Services; Subchapter A—General; Part 11—Electronic Records;

Ordering information

Amersham ImageQuant 800 GxP Software

Description	Product code
Amersham IQ 800 GxP E-license	29653452
Amersham IQ 800 Software Set*	29653453

* This is only necessary for existing users of Amersham ImageQuant 800 with software versions below 2.0.

Amersham ImageQuant 800 instrument only (PC not included)

Description	Product code
Amersham ImageQuant 800	29399481
Amersham ImageQuant 800 UV	29399482
Amersham ImageQuant 800 OD	29399483
Amersham ImageQuant 800 Fluor	29399484

External mini computer + PC accessories for ImageQuant 800

Description	Product code
ImageQuant 800 Mini PC and accessories	29428373

Image Analysis Software

Description	Product code
IQTL 10 GxP Node locked license	29655289
IQTL 10 GxP Floating license	29655291
IQTL 10 and IQTL 10 GxP Software Set	29655282

Optional accessories

Description	Product code
Amersham IQ 800 NP Lens	29399489
Amersham IQ 800 Custom filter holder	29399495

Upgrade modules*

Description	Product code
IQ 800 UV module	29424275
IQ 800 OD module	29424276
IQ 800 RGB module	29424277
IQ 800 NIR module	29424278

* OD, RGB, and NIR modules are available only for ImageQuant 800 UV configuration or above. Service charges are additional. Please contact your sales representative for more details.

IQ/OQ Offering

Description	Product code
IQ/OQ Amersham ImageQuant 800	29441929
IQ/OQ Amersham ImageQuant 800 UV	29441930
IQ/OQ Amersham ImageQuant 800 OD	29441931
IQ/OQ Amersham ImageQuant 800 Fluor	29441932
IQ/OQ Performance (1 Day)	28992654
CCP Amersham ImageQuant 800	29600588
IQ/OQ Performance (0.5 day)	28992659

Extended warranty and service offerings

Description	Product code
Amersham IQ 800 24 Month Warranty (12 Month Ext.) No PM incl	29435661
Amersham IQ 800 36 Month Warranty (24 Month Ext.) No PM incl	29435663
Amersham IQ 800 60 Month Warranty (48 Month Ext.) No PM incl	29435665

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