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Octet® BLI Compliance Software Frequently Asked Questions (FAQ)

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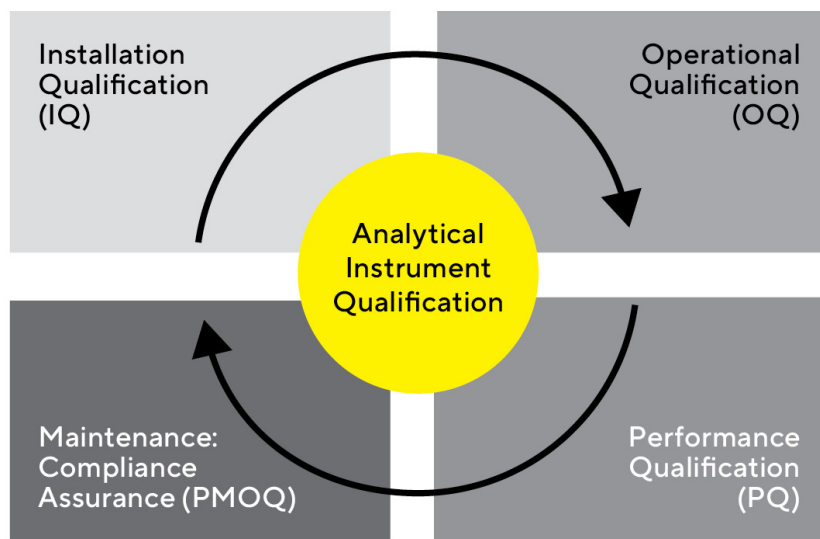
Introduction

GxP Compliance Tools for Octet® BLI Systems

From antibody quantitation, ligand binding characterization to potency assays, Sartorius offers a wide range of GxP compliance tools for developing validated assay methods on the Octet® BLI platform, including:

- Comprehensive tools for GxP compliance
- Simplicity in operations for analytical development and regulated quality control labs

Availability of a comprehensive tool set for compliance makes the Octet® BLI platform an ideal analytical instrument in regulated quality control (QC) labs for lot release and in-process testing for ligand binding, concentration, and impurity analysis in both upstream and downstream processes.



Sartorius Solutions for GxP Compliance

Compliant Installation and Operational Qualification (IQ/OQ) Kit and Services

The IQ/OQ kit provides comprehensive documentation to verify the Octet® BLI instrument, accessories and computer system are supplied and installed per Sartorius's guidelines by certified personnel. It also provides documented verification that the Octet® BLI instrument operates as intended at the user site by inspecting the critical components. These tests verify that the various key operational parameters, such as the optical system, plate temperature, system alignment, lamp performance, and shaker speed meet stipulated specifications.

Performance Qualification (PQ) Kits

PQ kits provide rapid and convenient methods to verify the performance of your Octet® R8, R8e and RH16 systems. PQ can be performed using one or two tightly controlled assays, depending on the instrument's intended use. The PQ-Kinetics and quantitation assays verify accuracy and precision of the assays are within specifications for a well-characterized model system pair.

Software Validation Package for Octet® Compliance Suite and Compliance Hub

For researchers working in GLP or GMP laboratories, the Octet® Software Validation Package provides the most comprehensive documentation and tools available to validate the Octet® Compliance Suite and Compliance Hub features and functions. It trims validation time to just three days using a fully integrated manual that mirrors the validation process in a regulated laboratory and provides sample data sets to authenticate analysis within Octet® software to traditional programs including Microsoft® Excel, and GraphPad Prism.

Biosensor Validation

This service enables Octet® BLI system users to sample multiple lots of a biosensor during assay qualification and validation and reserve a well-characterized lot for purchase. The service is available for the following biosensor types: Octet® ProA, Octet® SA, Octet® SAX, Octet® NTA, Octet® AMC, Octet® AHC and Octet® AHC2. Customers can order up to five different biosensor lots, up to 20 trays from each lot for evaluation, and reserve up to 40 additional trays for future purchase.

Software and Compliance – Frequently Asked Questions

1. How is the Octet® Compliance Suite software package different from the regular Octet® BLI Research Suite software?

The Octet® Compliance Suite Software package includes all features available in the regular Octet® BLI Discovery and Octet Analysis Studio software package but Octet® Compliance Suite and Compliance Hub Software has features to allow users to produce electronic records that meet the requirements of the FDA 21 CFR Part 11 Final Rule. This includes features such as administratively controlled application access, user group with defined access and roles, an audit trail, and electronic signatures of artifacts.

All Octet® R-Series BLI systems can use the Octet® Compliance Suite and Compliance Hub software package with basic Installation Qualification and Operational Qualification (IQ/OQ) and Performance Qualification (PQ). However, the Octet® R8, R8e and Octet® RH16 systems are better suited for a GxP environment due to the availability of extended IQ/OQ, and PQ packages that add more tests and documentation to verify the functioning of the systems and QC assay kits that generate automatic reports in the Octet® Analysis Studio Software.

2. Is the Octet® Compliance Suite software package compatible with Microsoft Windows 10 and 11?

Yes, Octet® Compliance Suite Software are compatible with Microsoft Windows 10 (64-bit) and Microsoft Windows 11 but older Microsoft Windows versions (e.g., Microsoft Windows 7) are not supported. Octet® BLI Software version 13.1 is also compatible with Microsoft Windows 11. Octet® Compliance Hub is supported on Microsoft Windows Server 2022 and 2025.

3. Is it possible to install the software on a terminal server or remote desktop server if users cannot install the applications on individual workstations ?

For Octet® BLI Discovery Software when recording data, the files should be stored to the local computer and after recording, the files can then be moved to a network drive for backup. The Octet® Analysis Studio Software can be installed on a server or workstation and then users can remote desktop to it. In both cases, the controller must not be attached to an Octet® BLI for this to work.

4. How many user accounts can be registered on an Octet® Compliance Hub?

There are no enforced limits. The practical limit is the space available on the server.

5. How are detailed histories recorded on the Octet® Compliance Hub?

Audit trails are recorded in the database managed by the Octet® Compliance Hub software. Each experiment has a unique identifier, and all data-specific audit trails are logged with the experiment identifier. Audit trails can be filtered by experiment, user, machine, project or date for viewing and printing.

6. Does Octet® Compliance Suite Software support data export for integration into LIMS?

Yes, Octet® Compliance Suite Software supports data export in CSV and Excel formats, which can be easily uploaded into many LIMS environments. Octet® Analysis Software can generate Excel, CSV, or PDF reports for import into your system. In addition, if your LIMS supports file attachments, you can also store method files and raw data within the LIMS for comprehensive data archiving.

7. Can you turn off specific feature(s) of the Compliance Suite software?

Octet® Compliance Suite Software features cannot be disabled. However, a user with the permission “Set commenting requirement” (see “Viewing and Changing Group Settings” in Octet® BLI Discovery User Guide 14) – can disable the commenting requirement in the Octet® Analysis Studio Software. All activities will still be logged to the audit trail, but this turns off the “enter reason” dialog that pops up whenever a change is made.

8. Is it possible to install the Octet® Compliance Hub and Octet® Research Hub on the same computer?

It is not possible to install both the Octet® Compliance Hub and Octet® Research Hub on the same computer. Octet® BLI Discovery and Analysis software features are dependent upon connection to the correct Octet® Hub.

9. Can an audit trail be Deleted? If so, will that leave a trace in the Octet® Compliance Hubserver?

Specific entries in the audit trail cannot be deleted by any means in the Octet® software.

Uninstall/reinstall also does not delete the audit trail. If you really need to delete the entire audit trail, you can do so if you are an IT administrator on the computer running the Octet® Compliance Hub. It is important note here is that here that “Administrator” refers to the Administrator to the PC (Windows PC), not the Octet® Compliance Hub server. Only the IT administrator can delete the audit trail database and there is no scheme for the Octet® Compliance Hub server administrator to delete the audit trail file.

The location of the file is provided in our documentation as it is desirable to create backups of the audit trail database. This is also why it is recommended that the Octet® Compliance Hub is installed on a separate computer from those running the Octet® BLI Discovery or Analysis Studio Software, this ensures that IT can safeguard any accidental deletion of the audit trail files.

Each organization must develop controlled, documented procedures for compliance with this requirement. It is the customer’s responsibility to administrate these documents.

10. What are the allowed user privileges?

The following default project roles are available once a project has been created by an Administrator. (Table 1):

- Project Owner - can review data and events.
- Scientist - can create, run, save and export data.
- Technician - can run experiments and analyze data.
- Viewer - can only view a project.

Additional groups with bespoke setting may be created by the administrator.

11. How can we authenticate Excel workbooks?

Octet® Analysis Studio Software generates a password-protected excel report sheets in which cells are protected and cannot be changed. However, in general we don’t provide a means to authenticate Excel workbooks. Once you export data to Excel you are outside of our CFR umbrella of data integrity. Sartorius does not consider this a data integrity defect.

Permission Name	Built-in Project Roles			
	Project Owner	Scientist	Technician	Viewer
View Project	Yes	Yes	Yes	Yes
Edit Project	Yes	No	No	No
Remove checkouts	Yes	No	No	No
Create and rename directories	Yes	Yes	Yes	No
Organize data	Yes	Yes	Yes	No
Archive and restore project data	Yes	No	No	No
Create and edit methods	Yes	Yes	No	No
Edit plate information	No	Yes	No	No
Run experiments	Yes	Yes	Yes	No
Analyze data	Yes	Yes	Yes	No
Build a multi-experiment analysis	No	Yes	No	No
Edit preprocess settings	No	Yes	No	No
Edit analysis settings	No	Yes	No	No
Exclude data from analysis	No	Yes	No	No
Edit report settings	No	Yes	No	No
Import analysis settings	No	Yes	Yes	No
Export analysis settings	No	Yes	No	No
Edit plate information when analyzing	No	Yes	No	No
Edit view properties	Yes	Yes	Yes	No
Export analysis results	Yes	Yes	Yes	No
Edit experiment information for analysis	No	Yes	No	No
Create and edit files	Yes	Yes	Yes	No
Sign document	Yes	Yes	Yes	No
Remove signatures from document	Yes	No	No	No

Table 1. Default Project Roles.

12. Are the audit trails on the Octet® Compliance Hub, Octet® BLI Discovery, and Octet® Analysis Studio software linked? How is the audit trail saved after the user logs out from the Compliance Suite software?

Yes, the audit trails are all stored on a single database that the Octet® Compliance Hub manages.

13. We currently have an older version of the Octet® CFR software in our development group and have released assays using the older version; When we purchase the new version of the software (version 14), do we need to re-qualify released assays? What is different between our old version and version 14?

You would need to re-validate the assay using the new software to ensure that the method under the new software is still fit for purpose. Please refer to version 14 software release notes for “what has changed”.

It is important to note that after upgrading to Octet® Compliance Hub, do not downgrade to a previous version of GxP server as there is a risk of data loss. Always make a backup of the database files before performing an update to the Octet® Compliance Hub software.

14. What happens if the customer (an administrator or any other group member) forgets the password to access the software?

Users and administrators cannot see an existing password. If a user forgets their password, the administrator cannot recover the lost password. The only solution is for the administrator to set a new password for the user. To prevent administrators from being locked out of the system, we recommend storing a written copy of the administrator password in a secure location and/or assigning a second person with administrator privileges so that if one administrator password is forgotten, the other administrator can reset the password. If the passwords for all administrator accounts have been lost or forgotten, please contact Octet technical support for additional options for restoring system access

15. Is Octet® Hub pre-installed when purchasing an Octet® instrument with Octet® Software v14? If not, who is responsible for installing and configuring it?

Octet® BLI Discovery and Octet® Analysis Studio are typically provided on the Octet® workstation, but Octet® Hub is deployed according to the customer’s selected configuration: Research Hub or Compliance Hub, and either an IT-managed server or local workstation. For server deployments, Sartorius recommends that customer IT install and configure Octet® Hub before the service visit when possible. This helps avoid delays related to server access, firewall/security settings, HTTPS/SSL, Active Directory/SSO, backup practices, and license activation. If Octet® Hub is not installed in advance, Sartorius can

support installation during the visit with customer IT participation. Detailed setup instructions are provided in the Octet® Hub User Guide.

16. How are the changes registered when the Octet® Discovery and Analysis software is not connected to the Octet® Compliance Hub?

If a computer cannot connect to the Octet® Compliance Hub, user activity is recorded and stored locally. When the computer re-establishes a connection with the Octet® Compliance Hub, the local stored events are uploaded to the Octet® Compliance Hub audit log database.

17. Can only administrators have access to the server and grant privileges?

Any user can log into the Octet® Compliance Hub administration tool. Unlike previous versions of the Octet® GxP software, Octet® Compliance Suite software separates permissions into Administrative or System level permissions, and separate Project permissions. Administrative permissions may be assigned to a specific user or group. Project Roles define a set of project level permissions. Project Roles are then assigned to a specific user or a group on a per-project basis, so a particular user could be a Project Owner for Project A, and only a Viewer on Project B (See Table 1).

It is also possible to have multiple project roles on the same project, and the permissions are the union of the permission sets. For example, a user could be both Project Owner and Scientist.

18. How does a customer transition from Octet® Research Suite to Octet® Compliance Suite? Can customers perform their own installation using a downloadable installer?

Customers can transition from Octet® Research Suite with Research Hub to Octet® Compliance Suite with Compliance Hub when regulated workflow controls are required. The transition should be coordinated with the customer’s IT, QA, and lab teams because it may involve Hub deployment, license activation, user/project setup, SOP updates, and customer-executed validation.

Customers may install Octet® Hub using the Octet® Hub User Guide, especially for IT-managed server deployments. Sartorius recommends customer IT perform the Hub installation in advance when possible, with Sartorius supporting installation verification, software launch, Hub connection, and instrument communication during the service visit. For regulated workflows, customers should use Compliance Suite connected to Compliance Hub and avoid using Research Suite for records intended to be governed under Compliance Suite controls.

19. Can users access the software if they do not have the privileges to run experiments or analyse data?

Yes, depending on their assigned privileges, they can use Octet® BLI Discovery and Analysis Studio Software. A user with no explicit privileges cannot access the software.

20. What happens if an experimental file is modified?

Modification of files outside the Octet® BLI software environment will cause the data integrity checks to fail. There is no recovery process.

21. Regarding the deployment options, which option is recommended?

Octet® Compliance Hub is deployed on-premise and can be implemented to match different lab structures and IT environments, from a single workgroup to multi-department or multi-site organizations. The best option depends on several factors including how users collaborate, how IT manages infrastructure and security. There are two options available to users: Option 1 is best for multi-user teams and regulated environments; Option 2 is best for small teams and pilots

Option 1 – Shared Octet® Hub on an IT-managed server (recommended)

In this model (Figure 1), Octet® Hub is hosted on a dedicated server environment managed by the customer's IT team. Scientists and teams connect to the same Hub to access shared projects, standardized methods, and centralized results from any authorized workstation. For IT, this approach supports central administration, user access management, and the establishment of backup and security practices.

Option 2 – Local Hub on a workstation

For small teams or pilot deployments, Octet® Hub can run on a designated "host" workstation without setting up a separate server (Figure 2). Users in the same workgroup can still benefit from project-based organization and shared access with minimal infrastructure. Because the Hub resides on a workstation, IT and the lab should align on host PC resources, uptime expectations, and backup practices.

Option 1 – Shared Octet® Hub on an IT-managed server (recommended)

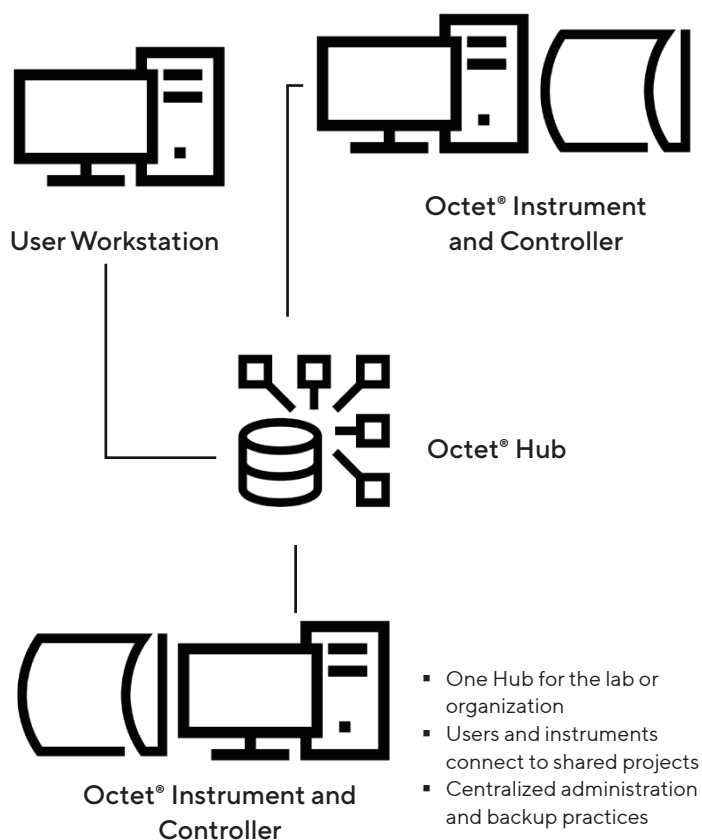


Figure 1: Network layout

Option 2 – Local Hub on a workstation

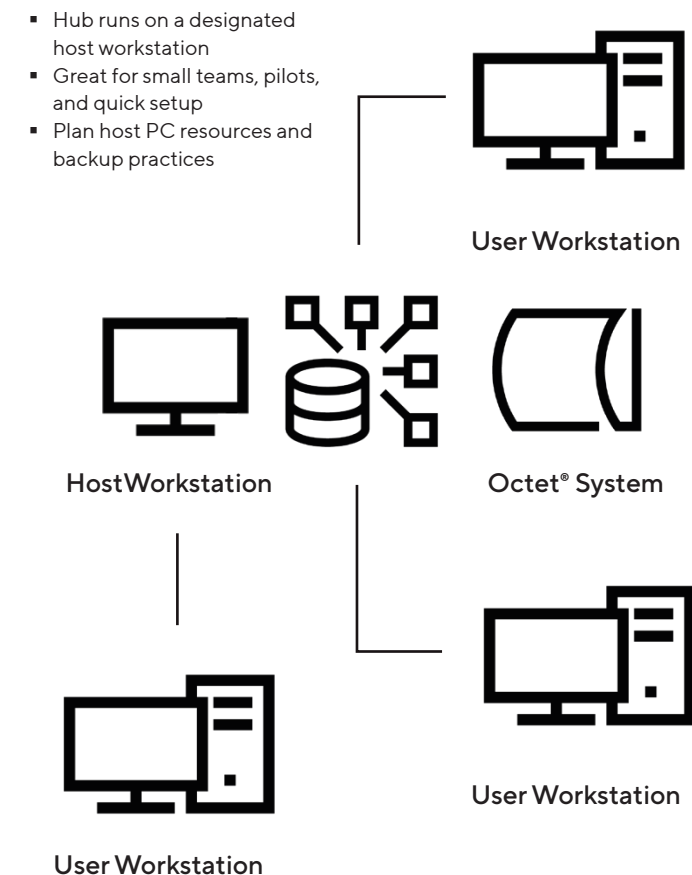


Figure 2: Local Hub on a workstation

Systems and Services – Frequently Asked Questions

22. Are the Octet® R2, R4, R8, R8e, RH16, and RH96 also GxP compliant and if so what IQ/OQ products do we use with them?

Yes, all Octet® BLI systems are GxP compliant (Figure 3). They are all compatible with Octet® Compliance Suite and Octet® Compliance Hub software. Each system has its own separate IQ/OQ guideline.

All Octet® R-Series BLI systems can use the Octet® Compliance Suite software package with basic Installation qualification and Operational Qualification (IQ/OQ) and Performance Qualification (PQ), but the Octet® R8, R8e, and Octet® RH16 are better suited for a GxP environment due to the availability of extended IQ/OQ, and PQ packages that add more tests and documentation to verify the functioning of the systems and QC assays kits that generate automatic reports in the Octet® Analysis Studio Software.

23. After IQ/OQ, what services are recommended by sartorius on an annual basis to maintain the system?

After installation and initial Operational Qualification (OQ), Instrument Preventive Maintenance (PM), and Performance Qualification (PQ), currently available only on the Octet® R8, R8e, and Octet® RH16 BLI systems are recommended on a planned/scheduled service interval as it removes the risk of the system and software being out of specification (OOS).

24. Does Sartorius offer an extended service for the GxP environment and what is handed over to the customer to verify that the service was performed according to GxP rules?

GxP customers can request a Performance Certification (PC) service or PMOQ service. A PMOQ service includes a Preventive Maintenance (PM) service with operational qualification (OQ) tests for a specific instrument type. In the case of the Octet® R8, R8e, and Octet® RH16 BLI systems, it also includes the Performance Qualification – Quantitation (PQ-Q) assay in addition to the two Performance Qualification – Kinetics (OQ-K) assays (see Figure 3).

25. How is the temperature of the plate determined for the systems other than Octet® R8, R8e, and Octet® RH16 BLI Systems? Is there an internal measurement of temperature?

During the assembly process, the heater plate temperature is verified to be within a window of 32.8 – 33.2°C. The plate's temperature is controlled using closed loop temperature controllers. The temperature is verified at manufacturing and during system preventative maintenance (PM) and Performance Certification (PC) described in question 24. A record of the value is created during PC.

26. How is the RPM of the shaker determined?

Shaker speed is controlled using a closed control loop that ensures that the shaker is operating within range. The shaker speed and % error is stipulated by the shaker manufacturer and is verified through a diagnostic software tool available on the system. Verification is done at Preventive Maintenance (PM) and during Performance Certification (PC). A record of the value is created.



Model	Octet® R2	Octet® R4	Octet® R8	Octet® R8e	Octet® RH16	Octet® RH96
GxP option	Yes	Yes	Yes	Yes	Yes	Yes
IQ/OQ Kit	41-0327	41-0326	41-0325	41-0332	41-0285	41-0217
IQ/OQ Service	84QAFR2	84QAFR4	84QAFR8	84QAFR8E	84QAF16	84QAF96
PQ Service	N.A.	N.A.	84QFFR8	84QFFR8E	84QBF16	N.A.
PMOQ Service	84MCFR2	84MCFR4	84MCFR8	84MCFR8E	84MBF16	84MBF96
Performance Qualification Bundle Kit	N.A.	N.A.	18-1178	18-5174	18-5140	N.A.

Figure 3: GxP compliant Octet® BLI systems

Assays and Method Development – Frequently Asked Questions

27. What key parameters need to be demonstrated in a GxP assay during method qualification?

These parameters are assay dependent and should follow regulatory requirements for the assay type. The determination of such parameters is the responsibility of the sponsor. Users interested in assay validation guidelines that can be used to develop well-qualified assays should see the Application Note [Harmonizing Regulatory Guidelines for Assay Validation: A Focus on Kinetics-Based Assays Using Octet® BLI Systems](#).

28. What type of assays is Octet® BLI currently utilized for in QC?

The Octet® BLI platform is used mainly for lot release and in-process testing assays. These are typically quantitation, potency assays, impurities testing or ligand binding assays.

29. Is BLI technology used in a current GxP compliant release process approved by the FDA?

There are several groups using the Octet® BLI platform for lot release assays. Organizations tend to keep certain information confidential and as a result, it may be difficult to point out specific accounts without their permission. The “Octet® BLI Characterization Data Used for Approved Drugs” table on the next page gives examples of cases in the public domain where Octet® BLI has been used to generate supporting data for regulatory submission of various products (Table 2).

30. How do we measure potency using the Octet® BLI? What are the reportable parameters?

Please see the Application Note [Octet® Potency Assay: Development and Validation Strategies](#).

Reportable parameters should be established by the sponsor but generally include % recovery and % CVs. K_D (Affinity) values can also be reported depending on the type of the method.

31. What is the accepted % CVs for a kinetics assay?

% CVs and other acceptance criteria are product dependent and should be set by the sponsor. Users interested in assay validation guidelines that can be used to develop well-qualified assays should see the Application Note [Harmonizing Regulatory Guidelines for Assay Validation: A Focus on Kinetics-Based Assays Using Octet® BLI Systems](#).

Drug Name	Target	Drug Modality	Sponsor	Regulatory Agency	Indications	Application	Year of Approval
Keytruda Pembrolizumab	PD-1	mAb	Merck	EMA	Non-small cell lung cancer	Affinity Characterization	2015
Tecentriq Atezolizumab	PD-L1	mAb	Roche	EMA	Non-small cell lung cancer	Specificity	2017
Comirnaty BNT162b2	COVID-19	mRNA Vaccine	Pfizer	EMA	COVID-19	Affinity Characterization	2020
Ultomiris Ravulizumab	Human C5	mAb	Alexion	EMA	Paroxysmal nocturnal hemoglobinuria (PNH)	Affinity Characterization	2019
Livogiva Teriparatide	PTH	Peptide Biosimilar	Teva	EMA	Osteoporosis	Affinity Characterization	2020
Atoltivimab, maftivimab, and odesivimab-ebgn	EBOV glycoprotein	mAb Cocktail	Regeneron	FDA	Ebola virus	Competition studies	2020
Oyavas Bevacizumab	VEGF-A	mAb Biosimilar	Mabxience	EMA	Non-small cell lung cancer	Specificity Affinity Characterization	2021
Jemperli Dostarlimab	PD-1	mAb	GSK	EMA	Endometrial cancer	Affinity Characterization	2021
Regdanvimab	S protein	mAb	Celltrion	EMA	COVID-19	Affinity Characterization Blocking Assay	2021
Xevudy Sotrovimab	S protein	mAb	GSK Vir Biotechnology	EMA	COVID-19	Affinity Characterization	2021
Nuvaxovid	COVID-19	Vaccine	Novavax	EMA	COVID-19	Affinity Characterization	2022
Kimmtrak Tebentafusp	CD3 gp100	TCR	Immunocore	EMA	Uveal melanoma (UM)	Specificity	2022
Tixagevimab Cilgavimab	COVID-19	mAb Combination	AstraZeneca	FDA	COVID-19	Affinity Characterization Blocking Assay	2022
Opdualag (nivolumab relatlimab)	LAG-3 PD-1	mAb Combination	BMS	EMA	Melanoma	Blocking Assay	2022
Briumvi ublituximab	CD20	mAb	Propharma Group	EMA	Relapsed Multiple sclerosis	Specificity Bridging	2023
Elrexio elranatamab	BCMA CD3	bsAb	Pfizer	FDA	Relapsed Multiple myeloma	Specificity Bridging	2023
Leqembi lecanemab	Aβ aggregates	mAb	Eisai	FDA EMA	Alzheimer's Disease	Specificity	2023 2024
Ahzantive aflibercept	VEGF-A PIGF	Recombinant fusion protein biosimilar	Klinge Biopharma	EMA	Retinal disorders	Specificity Blocking Assay	2024
Baiaam aflibercept	VEGF-A PIGF	Recombinant fusion protein biosimilar	Formycon AG	EMA	Retinal disorders	Specificity Blocking Assay	2024
Epruvy ranibizumab	VEGF-A	mAb fragment biosimilar	MIDAS Pharma	EMA	Retinal disorders	Specificity Blocking Assay	2024
Tuznue trastuzumab	HER2	mAb biosimilar	Prestige Biopharma	EMA	Breast and gastric cancer	Specificity Blocking Assay Bridging	2024
Anktiva Nogapendekin alfa inbakicept	IL-15 Receptor	Recombinant fusion protein complex	ImmunityBio	FDA EMA	Bladder cancer	Specificity Agonism Bridging	2025
Dazublys trastuzumab	HER2	mAb biosimilar	CuraTeQ Biologics	EMA	Breast and gastric cancer	Specificity Blocking Assay Bridging	2025
Exdensur depemokimab	IL-5	mAb	Glaxosmithkline	FDA EMA	Asthma	Specificity Blocking Assay	2025
Gotenfia golimumab	TNFα	mAb biosimilar	STADA Arzneimittel AG	EMA	Rheumatoid arthritis	Specificity Blocking Assay Bridging	2025
Teizeild teplizumab	CD3α	mAb	Sanofi Winthrop	EMA	Type 1 diabetes	Specificity Agonism	2025
Usymro ustekinumab	p40	mAb biosimilar	Elc Group	EMA	Plaque psoriasis	Specificity Blocking Assay	2025

Table 2. Examples of approved drugs utilizing Octet® BLI data in their applications. This table includes examples of drugs where the Octet® BLI system has been used to generate data submitted as part of the supporting information for the drug's approval with regulatory bodies.

Germany

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