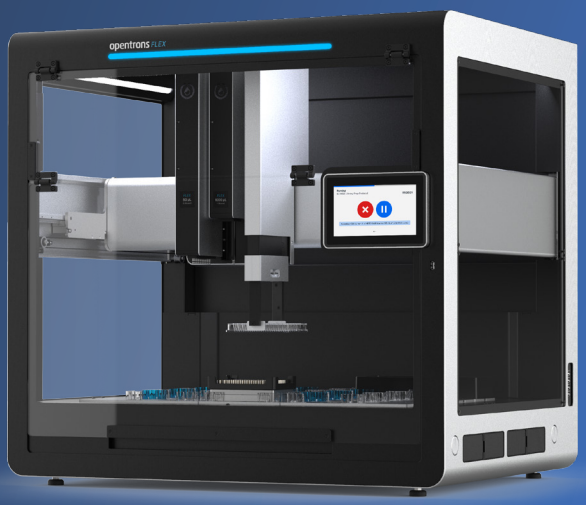
Be audit-ready, automate on the Opentrons Flex®.

Compliance Ready Software delivers the technical controls for 21 CFR Part 11. Your SOPs and validation practices do the rest.



Compliance ready by design

What Compliance Ready Software provides:

The technical controls 21 CFR Part 11 mandates - authentication, audit trails, access controls, and electronic record integrity - are built into the platform.

What your team brings:

The SOPs, validation protocols, and data management practices that operationalize those controls in your workflow. We can help you build them.

Access and authority controls

- Role-based permissions define what each user can operate, modify, or access
- Shared accounts are structurally prevented; every interaction requires unique credentials
- Only authorized users can initiate a run, alter a work flow, or perform a controlled action

Secure audit trails

- Every run automatically logs who acted, what ran, and when
- Records are cryptographically signed and tamper-proof, no user, including administrators, can alter an entry
- Logs are retained in full and available for FDA inspection at any time

Validated system controls

- Compliance mode is irreversible once activated; SSH and Jupyter access are permanently disabled
- Only administrators can modify system configuration or security policies
- Validated workflows are enforced at the platform level and cannot be altered by users

Electronic record integrity

- Every record is linked to the individual who created or approved it, with name, timestamp, and action captured at signing
- Records cannot be copied, transferred, or altered in ways that falsify the original
- All records remain readable and retrievable for FDA inspection for their full retention period

Schedule a **compliance conversation**

email: info@opentrons.com
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Compliance Ready Software	Part Number	Price
Set-up | Activation | Training	303-00003	$14,975