



# GxP Readiness Kit

- Peace of mind, hassle-free pack. Let us help you with compliance.

Adherence to compliance with GxP is mandatory for everybody working in regulated environments such as those in the development or manufacturing space of the pharmaceutical industry including CROs, CMOs and other service providers. Important requirements are data integrity and instrument qualification.

Data integrity (DI) is fundamental to the consistent supply of quality medicines and a hot topic for regulatory authorities who actively look for DI issues when conducting inspections and reviews. We have implemented a DI framework, aligned to the very best industrial practice.

Superior level of compliance is achieved with a software suite directly analogous to the accepted standard for GxP operations, offering secure access to the instrument and the option to manage one or more instruments in a network, under GxP.

## Your Benefits

- Log in and out without compromising acquisition and attrition, with a new web interface designed for experiment submitting and laboratory management under GxP
- Exquisite control over users, their rights and roles
- Data securely stored in a database
- Detailed audit trails (what, who, when...) in human readable format, formatted for easy visualization
- Several workflows are supported, adapting to the different users' ways of working
- Approval workflows and electronic signatures
- Smooth integration of additional spectrometers whilst ensuring the integrity of previously obtained data and audit trails

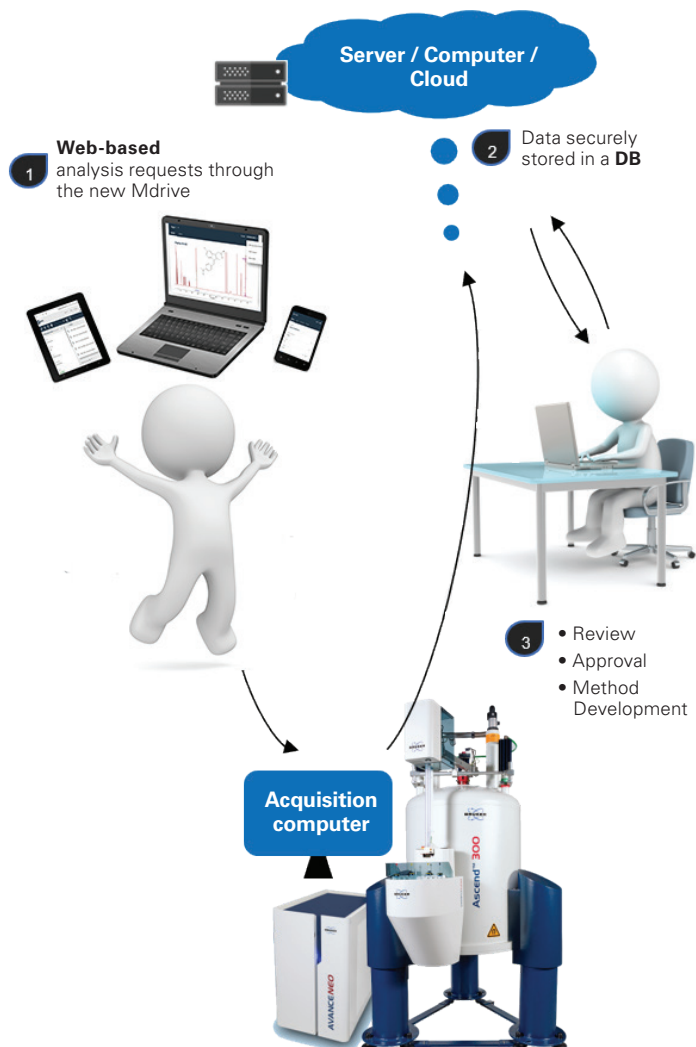
## Key Components

- IQ & OQ protocols completed by our qualified engineers
- PQ supportive software (systems suitability)\*
- Certified samples
- Enterprise software platform designed for state-of-the-art 21 CFR part 11 compliance
- Computer system validation protocol
- 21 CFR part 11 manual
- Validation and GAMP certificates
- Installation and training by GxP qualified engineers

## Compatibility

- NMR spectrometers with AVANCE NEO console, equipped with either liquids or solid probes
- Fourier 80 spectrometers

\* PQ supportive software currently only included in GxP Readiness Kit NEO



**DRIVE** Desk Team Clients **Laboratory** Messages 76 Audit trail axc (Analysis Manager)

Mockup spectrometer (Instrument)	Service	Description	Status	Open a
Code mockupspectro	NMR - HMBC - Structure Elucidation	HMBC with 16 scans for structure elucidation	Active	Yes
Technique NMR	NMR - COSY - Structure Elucidation	Cosy with 2 scans for structure elucidation	Active	Yes
Type NMR Spectrometer	NMR - 1H - Structure Elucidation	Proton with long d1 for structure elucidation	Active	Yes
Parameters Field: 400 MHz	NMR - 15N-HMBC - Structure Elucidation	15N HSQC/HMBC with 36 scans for structure elucidation	Active	Yes
Status Operational	NMR - HSQC - Structure Elucidation	HSQC with 4 scans for structure elucidation	Active	Yes

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