PHARMA TECHNOLOGY

QC Innovation Spotlight

8 things carefully look when choosing a new OSD CQAs analyser

There are many factors to consider when investing in new tablet testing equipment. This document outlines eight key criteria to help guide the selection of an oral solid dosage (OSD) CQA analyser.

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INTRODUCTION

Tablet & Capsules testing is a critical discipline across the entire manufacturing spectrum—from early R&D through commercial production—providing a complete set of tablet Critical Quality Attributes (CQAs) that confirm the physical and chemical performance of the final dosage form administered to patients.

By leveraging advanced testing systems and PAT tools, formulation and process scientists can generate high-value data that strengthens understanding of formulation behaviour relative to Critical Process Parameters (CPPs), supports Design of Experiments (DoE), and reinforces Quality by Design (QbD) strategies.

A robust and reliable testing platform should be fully scalable to commercial environments, enabling smoother technology transfer, enhanced In-Process Control (IPC), and more consistent Continued Process Verification (CPV). Moreover, real-time analytical capability can accelerate Real-Time Decision-making (RTD) and support Real-Time Release (RTR) of finished product.

Summary of the most tested CQAs

Category	CQA	Purpose
Physical	Appearance, Weight, Hardness, Friability	Uniformity, handling, and physical integrity
Performance	Disintegration, Dissolution, Content Uniformity	Drug release and bioavailability
Chemical	Assay, Impurities, Moisture	Potency, safety, and stability
Microbiological	Bioburden, Pathogens	Product safety
Formulation-specific	Coating, Polymorph, Particle Size	Controlled release and stability

API fraction | Mass | CU & Assay | Hardness | Thickness | Diameter | Length | Moisture | Porosity | Temperature

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TODAY'S CRITICAL QUALITY ATTRIBUTES (CQAS) — AND TOMORROW'S REQUIREMENTS

The development of OSD products is driven by a constant tension between speed, reliability, and regulatory compliance.

Formulation scientists often work with APIs that present poor solubility or stability, requiring tailored excipient combinations. During early development, limited data derived from destructive sampling makes it difficult to fully understand powder or tablet uniformity.

Detectability studies must confirm whether the active pharmaceutical ingredient (API) can be reliably identified within a complex formulation. Yet these studies, when performed with traditional methods, are often slow and resource-intensive.

CQA	Related Process Step(s)	Key CPPs*	Impact
Tablet Weight / Weight Uniformity	Blending, Compression	Blend uniformity, feed frame speed, turret speed, die fill	Influences uniform dose per tablet.
Thickness & Diameter	Compression	Compression force, fill depth, tooling dimensions	Directly affects tablet dimensions and packaging fit.
Hardness / Crushing Strength	Compression	Compression force, dwell time, granule moisture, particle size	Affects mechanical strength and dissolution rate.
Friability	Compression	Compression force, lubrication time, granule density, moisture	High friability indicates weak tablets prone to breakage.
Disintegration Time	Granulation, Compression, Coating	Binder concentration, disinte-grant level, compression force,	Impacts how quickly the tablet breaks apart in GI fluids.
Dissolution Profile	Granulation, Compression, Coating	Binder/disintegrant ratio, par-ticle size of API, compression	Directly linked to bioavailability and release kinetics.
Content Uniformity	Blending, Lubrication, Compression	Mixing time, blender speed, lubricant blending time, segre-	Ensures consistent API content across tablets.
Assay / Potency	Raw material control, Blending, Compression	API assay, blend uniformity, compression uniformity	Determines accurate dosage strength.
Impurities / Degradation Products	Granulation, Drying, Compression, Coating	Drying temperature/time, lubrication time, coating tem-perature, storage humidity	Excess heat or moisture can lead to API degradation.
Moisture Content (LOD / KF)	Drying, Coating, Packaging	Drying temperature/time, inlet/outlet air temperature,	Impacts stability, dissolution, and microbial growth.

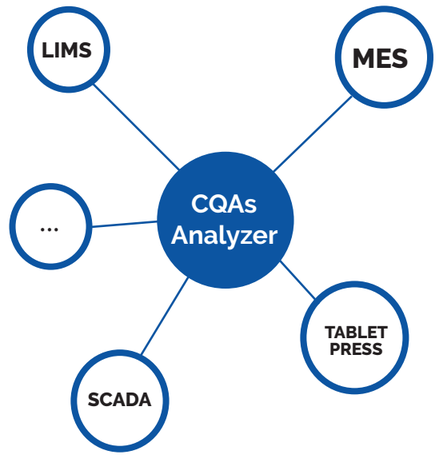
* Critical Process Parameters

It is expected that the sample quantity, frequency, and CQA's expectations will increase in future regulatory guidance. It is highly likely that the authorities' requirements will become more stringent in terms of testing, such as determining the CU by correlating the individual mass with the individual % of APIs in tablets or capsules.

2

INTEGRATION WITH EXISTING EQUIPMENT AND DIGITAL INFRASTRUCTURE

A next-generation analyser should align with your current manufacturing and R&D environment. This includes compatibility with existing tablet presses, capsule fillers, conveyors, and sampling systems, as well as smooth connection to MES, LIMS, SCADA, and historian platforms. Seamless digital integration reduces validation burden, simplifies data governance, and ensures that high-frequency PAT data can be efficiently digested by multivariate control systems.



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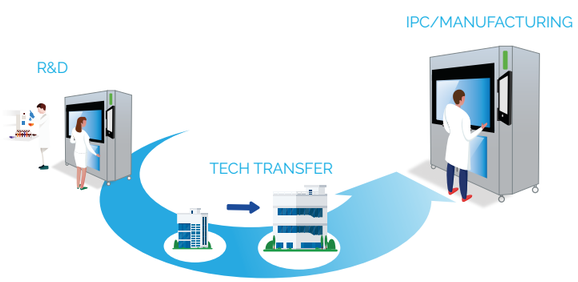
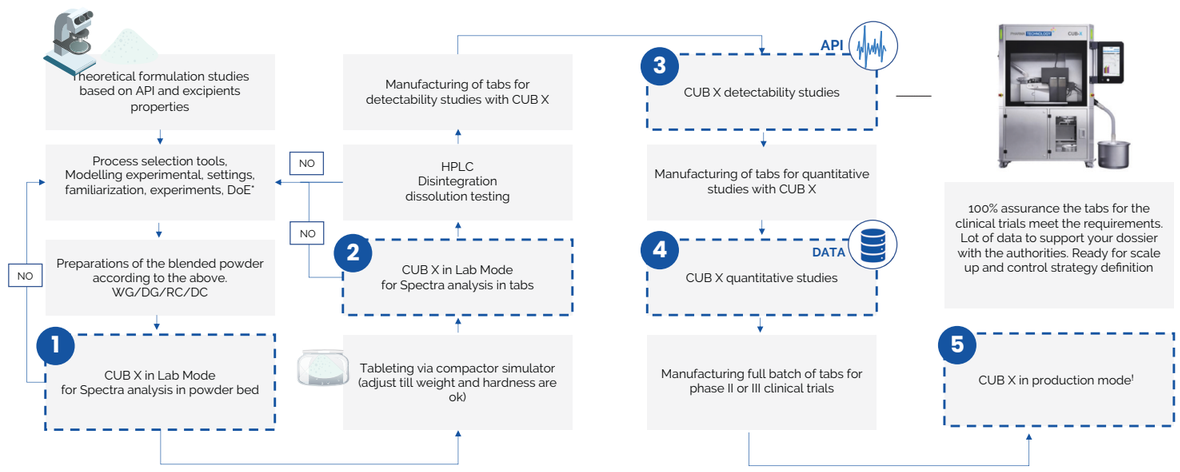
SCALABILITY

Scaling up a control strategy from R&D to Commercial Manufacturing can be challenging, with formulation problems likely to arise in the form of tablet non-conformity. Advanced PAT analyser helps to prevent issues by getting the CQA's data in real-time – not waiting from long analysing process. Modern analysers can deliver accurate, real-time predictions of key CQAs on both small laboratory single-punch presses and high-speed commercial production lines, ensuring consistent performance and a smoother scale-up pathway.

This allows perfect scalability between R&D - Pilot - Tech Transfer - Commercial Manufacturing. The system being independent from the line, it can be easily transferred from one department to another, or even from one site to another.





* *Fully Automated and DoE-Based Development of an Oral Solid Dosage Form (T.Brinz et al.)*

† *Towards real-time release of pharmaceutical tablets: 100% in-line control via near-infrared spatially resolved spectroscopy and 3D microwave resonance technology* (Krume et al. 2021)

CUB-X CQAs analyser used at R&D for product development

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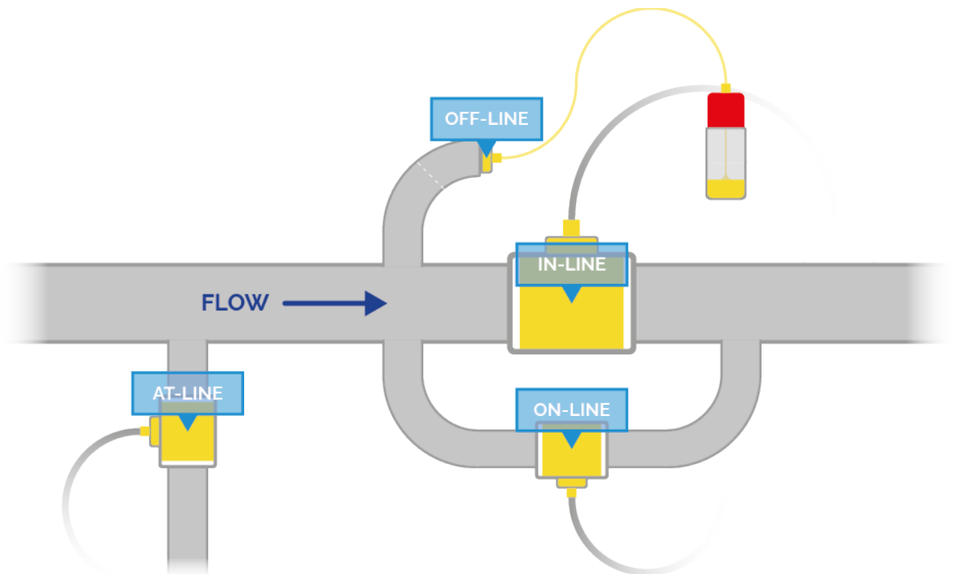
VERSATILITY & FLEXIBILITY

Next-generation analysers are designed with versatility and mobility at their core, enabling seamless deployment across global R&D and manufacturing networks. Whether used in early formulation labs, pilot-scale environments, or high-throughput commercial sites, these systems adapt easily to different equipment, product types, and regulatory expectations. Their modular architecture, compact footprint, and compatibility with multiple tablet presses and capsule fillers make them easy to relocate, requalify, and integrate into diverse production setups. This flexibility ensures companies can standardize analytical methods worldwide, streamline technology transfer, and maintain consistent CQA monitoring regardless of location—supporting a truly scalable global manufacturing strategy.

Here are some examples of flexibilities:

- Selection of the **needed CQAs needed for a particular product**
- **Various way of testing:** powder cup, single object First-in/First-out, multiple tablets or capsules
- **Testing strategy:** frequency of sampling, quantity per sample set, as well as a First In/Fist Out mode (FIFO) is also available to keep track on each object tested.
- **Mobile QA Strategy scalable to the world:** new generation of PAT analyser are mobile and process line supplier agnostic. They can be use in various configuration. They are easy transferable from site to site following the product (i.e. product transfer to CDMO). In other words, they can follow the product anywhere in the world and on any kind of processing line.
- **Various control strategy:** Off-Line, At-Line, On-Line, and In-Line



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PAT ROBUSTNESS – EASE OF USE WITH NO SPECIALIST REQUIRED

While PAT technologies for tablet and capsule characterization are inherently sophisticated, they should feel simple and intuitive to the people who use them every day. Many vendors claim to offer user-friendly software, but true ease of use is demonstrated by how robustly the system performs under real operational conditions -and how little specialized expertise is required to keep it running.

At Pharma Technology, this philosophy has guided product development from the beginning. “Let’s create a machine that a trained operator can use - from R&D to commercial manufacturing - without needing a PAT expert for routine operation,” says Martial DOLLINGER, CEO of Pharma Technology.

Achieving this level of accessibility requires more than a clean interface. It involves supporting the entire workflow: from setting up DoE studies, configuring the equipment, and tagging samples, to data acquisition, ordination, storage, and chemometric model application—all the way through to day-to-day routine operation.

The CQAs analyser software must be built for flexibility, allowing users to access straightforward visual outputs such as pass/fail indicators, statistics, or histograms, while still offering deeper access to raw data, spectral analysis, and advanced diagnostics when needed. Every step has been deliberately engineered around user requirements, ensuring that complex PAT capability is delivered through a stable, industrial, robust, and operator-friendly solution.

Summary of the task, personal, and relevant process:

CQA	Related Process Step(s)	Key CPPs*
DoE plan	Scientist	Easily introduced in the analyser software through an
Data set run for models	Trained operator	ID tag label creation, assisted test product sequence
Data collection	Machine	Organized XML file exported on a server
Chemometrics modelling	Scientist / chemometrician	Chemometric model
Feed the machine with the model	Scientist / chemometrician	Security of the model transfer
Routine run of the machine	Trained operator	Immediate prediction, Real Time Decision (RTD), In Process Control (IPC), Continued Process Verification (CPV), Automated Process Control (APC)

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DATA INTEGRITY & AUTOMATED CONTROL LOOP

A key advantage of next-generation CQA analysers is their ability to capture large volumes of high-frequency data in a secure, structured, robust and traceable manner. This capability delivers value across the entire lifecycle from early R&D, where rapid experimentation is essential, to commercial manufacturing, where consistent, compliant data streams support robust process monitoring. By consolidating CQA information into a unified view, these systems simplify interpretation and enable faster Real-Time Decisions (RTD).

For every monitored CQA, the system should provide immediate visualization, including individual measurements, statistical summaries, and histogram displays. Secure, real-time data exchange with central databases is enabled through OPC UA communication, while local logbooks and reports can be instantly generated and digitally signed to meet data-integrity expectations.

Beyond analytics, the platform must communicate directly with upstream or downstream equipment to support a fully automated control loop—allowing critical process parameters (CPP) to be adjusted in real time based on live CQA feedback, strengthening process robustness and paving the way toward Real-Time Release (RTR).

The analyser should feature a dust-tight design, with the testing area maintained under light negative pressure to ensure maximum operator safety. For handling highly potent or toxic compounds, Pharma Technology provides analysers configured to meet a range of Operator Exposure Band (OEB) security levels, guaranteeing compliance with strict safety standards while maintaining reliable testing performance.

OPC UA
CONTROL LOOP

TABLET PRESS

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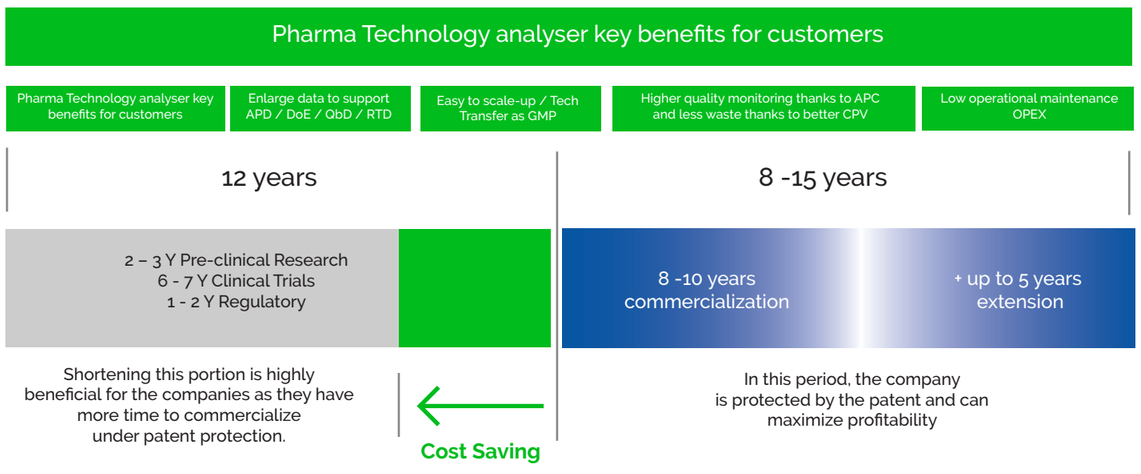
RETURN ON INVESTMENT (ROI)

While initial cost is always a consideration for pharmaceutical laboratories, the true value lies in the return on investment. The right tablet analyser can generate significant cost savings by providing comprehensive data acquisition and analysis capabilities. This enables a deeper understanding of tablet quality, supports the development of more robust formulations, and reduces defects and downtime during production.

Next-generation PAT analysers accelerate development work across production equipment, offering multiple tangible benefits: reduced material consumption during R&D, streamlined support for Design of Experiments (DoE) and Quality by Design (QbD) with instant CQA's access, smoother scale-up to commercial manufacturing, enhanced In-Process Control (IPC), and faster batch release. Together, these efficiencies translate directly into operational cost savings and a faster, more reliable path from R&D to market-ready products.



CONCLUSIONS - reducing time to market for OSD pharmaceutical products is critical to:

- ✓ Minimize Material consumption during R&D
- ✓ Maximize patent life and revenue potential.
- ✓ Strengthen competitive positioning.
- ✓ Recover R&D investments efficiently.
- ✓ Meet urgent patient needs and align with regulatory priorities.

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STRONG SERVICE NETWORK

Routine maintenance is critical to ensure that your analyser delivers reliable performance throughout its lifespan. Typically, this involves simple calibration or the replacement of standard wear parts, but as our technical experts emphasize, "rapid response in case of issues is essential." In the fast-paced pharmaceutical environment, delays from your equipment partner can lead to costly downtime and setbacks.

Over the years, Pharma Technology has expanded its global presence, providing customers with access to worldwide service teams and strategically located spare parts. Tablet & capsules testing specialists are positioned around the globe to maintain equipment, train users, and help clients fully leverage their investment.

What ultimately counts is not just service availability, but the depth of scientific expertise behind the technology. Can their team communicate effectively with your scientists? Are they simply delivering a machine, or are they also enabling your team to master it?

At Pharma Technology, our foundation in pharmaceutical process equipment, combined with R&D scientists who work daily with our Quality Control systems, ensures that our solutions are both practical and scientifically rigorous. Additionally, we support a broad community of academic and industrial researchers through experimental studies and model development. The scientific expertise within the Pharma Technology Research team is a key driver of successful partnerships and innovative solutions across the industry.

Martial Dollinger
Pharma Technology 's CEO

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