



PHARMA CONCEPTS

MEASUREMENT IS BECOMING THE
DIFFERENTIATOR

How Irish Pharmaceutical Manufacturing Is Quietly
Changing, and What Many May Have Missed.

Executive Summary



Introduction

Ireland's life science sector continues to grow in scale and complexity. New facilities, new therapies, and new expectations are arriving at the same time. Publicly, the conversation focuses on investment announcements, job creation, and capacity expansion. Inside manufacturing and quality teams, a different conversation is happening.

The real pressure is not volume.

It is control.

Pharma Concepts

Shares Antech's perspective on trends shaping pharmaceutical manufacturing today. Some are widely discussed. Others are happening in the background and are only noticed when something goes out of spec. Together, they point to a simple conclusion.

Measurement is no longer just a quality function.

It is becoming the differentiator between sites that struggle and sites that lead. This paper focuses on Ireland first, with global context where it matters, and is written for people responsible for quality, manufacturing, MSAT, and operations who need insight they can act on.

A Message from Dermot Harrington, MD, Antech

Overview



“We believe Pharma Concepts speaks directly to what many pharmaceutical teams are feeling but not expressing out loud. Over more than three decades working with quality, manufacturing and MSAT teams, I have seen how measurement, understanding and timely insight can make the difference between constant firefighting and smooth, confident operations. We wrote this paper in an attempt to help teams see beyond the obvious trends and focus on the practical shifts that matter now in Ireland and beyond. We created it to support teams in making better decisions, faster, and with evidence they and their auditors can trust.”

Core Values

- Innovation: Advance products through R&D and AI. — AI-driven features (smarter peak detection).
- Sustainability: Design to minimise waste & time. — ReSolve recovers >90% of HPLC solvent.
- Excellence & Quality: Deliver compliant, best-in-class solutions. — Maintain CQAs and DATA INTEGRITY.
- Customer-centric & Compliant: Solve customer needs with reliable, compliant service. — verify/qualify
- Continuous Improvement: Use Lean + data to get better fast. — Kaizen, Lean/6-Sigma and analytics.

Manufacturing Reality

Overview

Ireland remains one of the most important pharmaceutical manufacturing hubs globally. Biologics, small molecules, advanced therapies, and high value secondary manufacturing all coexist within a relatively small geographic footprint. The concentration of expertise is a strength, but it also creates pressure.

Facilities are larger and more complex than they were ten years ago. Product portfolios are more diverse. Batch sizes are moving in both directions at once, with blockbuster volumes on one line and smaller, high value batches on another. Supply chains are more fragile, even when suppliers are well qualified.

At the same time, teams are leaner.

Many Irish sites are managing growth while onboarding new staff, integrating new technologies, and absorbing regulatory change. The result is that processes which once relied on experience, judgement, and sampling are now being asked to operate with much tighter margins for error.

This is where measurement enters the conversation.

Not measurement as an abstract concept, but measurement that happens close to the point of decision. Measurement that reduces uncertainty rather than adding complexity. Measurement that operators, quality teams, and auditors can trust.

[EU GMP Principles on Pharmaceutical Manufacturing](#)

Market Analysis

How we built these insights



The perspectives in this paper come from three sources.

First, regulatory signals. Updates to EU GMP expectations, particularly around sterile manufacturing and contamination control, are changing what inspectors ask for and what they accept as evidence. International guidance on continuous manufacturing has matured, shifting the conversation from whether it is allowed to how it should be implemented.

Second, what we see across Irish manufacturing operations. Antech works with Pharma and biotech companies across Ireland and the UK, supporting quality control, manufacturing, and process development teams. We see where processes slow down, where investigations get stuck, and where teams struggle to generate confidence quickly.

Third, global trends that are landing locally. Nitrosamine risk management, PFAS restrictions, data integrity expectations, and counterfeit detection initiatives are not abstract regulatory topics. They show up in real workflows, procurement decisions, and audit questions.

These insights reflect what is happening now, not what might happen in five years.

Ten trends reshaping pharmaceutical manufacturing



1. Control is replacing compliance as the real inspection focus

- Procedures are still necessary, but they are no longer sufficient. Inspectors increasingly want to understand how contamination and process risks are identified, monitored, and controlled in practice. This is especially true in sterile and aseptic environments, but the thinking is spreading more broadly.
- What matters is not whether a control strategy exists on paper, but whether it produces evidence that risk is understood and managed.
- Irish sites that rely heavily on periodic sampling and retrospective review are finding this harder to defend. Sites that can show real time or near real time insight into materials and processes are finding conversations move faster.

2. PAT programmes succeed when they start small

- Process Analytical Technology has been discussed for years, yet many programmes stall. The most common reason is scope. Trying to monitor everything at once creates complexity that teams struggle to sustain.
- The sites making progress are starting with a single, well defined endpoint. Blend uniformity. Drying completion. Concentration during a critical step. When that endpoint proves its value, it earns trust. From there, expansion becomes easier.
- This approach aligns well with the realities of Irish manufacturing, where change control discipline and validation resources are finite.



3. Raw material identity may no longer be enough

- Passing identity tests at receipt does not guarantee consistent behaviour in process. Subtle changes in raw materials, particularly excipients, can alter flow, compression, dissolution, or stability. These changes often sit within specification and only become visible when a downstream issue appears.
- Forward looking sites treat raw material checks as an opportunity to detect drift, not just confirm identity. This shifts raw material testing from a gatekeeping activity to an early warning system.

[USP's excipient quality and supplier risk guidance](#)

4. PFAS restrictions will affect laboratories before factories



- Discussions around PFAS often focus on environmental controls and firefighting foams. In practice, laboratories will feel the impact earlier. Consumables, coatings, tubing, and sample contact materials are all potential exposure points.
- Irish pharmaceutical labs that begin mapping these touchpoints now will avoid rushed substitutions later. This is a quiet area of risk that is easy to overlook until procurement options narrow.

[EPA Ireland information page on PFAS restrictions](#)

5. Continuous manufacturing is now a capability question

- International guidance has clarified how continuous manufacturing can be developed and operated within a compliant framework. The barrier is no longer regulatory acceptance. It is organisational readiness.
- Continuous manufacturing demands confidence in measurement, control strategies, and response plans. Teams need to know how they will detect deviation, how quickly they will act, and how decisions will be documented.
- Sites with strong measurement foundations are better positioned to explore these models without disruption.

6. Digital transformation is becoming operator focused

- The next phase of digital manufacturing is not about dashboards. It is about reducing ambiguity and ease of use at the point of action.
- When operators are asked to make frequent judgement calls, variability increases. When measurement provides clear pass or fail signals, processes become more consistent and training burdens fall.
- This is where simple, robust analytical tools deliver disproportionate value. Not because they are sophisticated, but because they are trusted and easy to use.

7. Sustainability is being driven by quality efficiency

- Environmental impact is not only about energy use. In pharmaceutical manufacturing, waste often comes from rework, repeat testing, and investigation driven scrap.
- Reducing unnecessary sampling, avoiding failed batches, and shortening investigations all reduce environmental impact while improving performance. Measurement that prevents problems rather than detecting them later supports both objectives.

8. Release is evolving quietly

- Real time release remains a long term goal for many products, but a more immediate shift is happening. Release by exception. Reduced testing where processes demonstrate stability. Greater reliance on process knowledge.
- These approaches only work when measurement is consistent and defensible. Sites that invest early in reliable process monitoring find it easier to justify leaner release strategies later.

[Take a Look at the Antech website](#)

9. Small batches are changing how quality is assured

- Advanced therapies and niche products bring small batch sizes with high value. Traditional sampling strategies can consume a significant portion of a batch and introduce risk.
- Non destructive analytical approaches allow quality checks without sacrificing material. This is becoming increasingly important as product portfolios diversify.



10. Tech transfer readiness is a competitive advantage

- Ireland's role as a global manufacturing hub means sites are regularly asked to accept new products and processes. Speed matters, but so does confidence.
- Sites that can quickly establish material identity, confirm process endpoints, and demonstrate control reduce transfer timelines and attract future work. Measurement capability plays a central role in this readiness.

What this means for Irish pharmaceutical teams

Taken together, these trends point in one direction.

Manufacturing success is becoming less about scale and more about certainty.

- **Certainty in raw materials.**
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- **Certainty in process behaviour.**
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- **Certainty in decisions made under pressure.**

Irish sites that invest in measurement close to the point of risk are finding it easier to respond to regulatory expectations, support growth, and manage complexity without adding layers of bureaucracy.



At Antech,

we work with life science teams who want practical solutions, not theory.

Our focus is on bringing reliable analytical capability into everyday workflows without compromising compliance.

That includes supporting handheld and portable spectroscopy for material verification, process analytical technologies for in process understanding, and the training and qualification that allow teams to use these tools with confidence.

We see measurement working best when it is simple, well governed, and clearly linked to decisions. When that happens, it stops being seen as an extra step and starts becoming part of how work gets done.

[Learn More about our Handheld and Portable Spectroscopy.](#)

Conclusion

The pharmaceutical industry in Ireland is moving quickly, and the direction of travel is clear. Growth continues, but the expectations placed on manufacturing and quality teams are becoming more demanding.

From what we see across the industry, the sites that perform best are not those doing more laboratory testing, but those reducing uncertainty and making decisions with confidence.

Measurement sits at the centre of that shift, not as an added burden, but as a practical way to bring clarity to increasingly complex processes.

We hope this paper has helped highlight where these changes are really happening, including some that are easy to overlook until they become challenges. If it has sparked new thinking, we encourage you to share it with colleagues who are navigating similar pressures.

At Antech, we created this to support the teams doing the work every day. If you would like to explore solutions for your challenges, or discuss how improved measurement could support your site, we would welcome the opportunity to talk.

To learn more about how Antech works with pharmaceutical teams across Ireland and the UK, or to get in touch with our specialists, visit www.antech.ie.

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