APPRENTICE

# What Is a Next-Gen MES?

**Read our eBook to learn:**

- **What a next-gen MES is not**
- **What it is and how it works**
- **Guidelines and examples on how to access its full potential**

# Table of Contents

# Executive Summary

In this eBook, I'll break down the definition, value, and features of next-generation MES for pharmaceutical manufacturers.

But first, let me introduce myself.

My name is Emilee Cook, and I'm a Director of Product here at Apprentice.

I have over a decade of experience in the life science industry, and I'm inspired by the potential of technology to completely transform this space.

Which brings me to this eBook — it doesn't get more transformative than next-gen MES!

On the following pages, I'll start by covering an especially crucial question — what *isn't* a next-gen MES?

I'll then explain what a next-gen MES is and how it works.

Last, I'll consider the unique value next-gen MES can provide for pharma manufacturers. Let's dive in!

CHAPTER ONE

# What Isn't a Next-Gen MES?

First things first, let's get straight on what a next-gen MES is *not*.

- X It is **not**... putting MES in the cloud.
- X It is **not**... adding AI into or on top of MES.
- X It is **not**... putting predictive analytics in MES.
- X It is **not**... sticking a pretty interface on top of MES.
- X It is **not**... simply getting all your data into a hub.
- X It is **not**... a magical one-size-fits-all data model.
- X It is **not**... no-code apps that people can build.
- X It is **not**... building a licensing model for an MES.

Those who make, or hear, such statements should give pause.

The equation for a next-gen MES is not simply: MES functionality + a certain technology or trend.

If it were that simple, it would have been done years ago... and we wouldn't even be discussing this concept to begin with!

CHAPTER TWO

# What Is a Next-Gen MES?

A next-gen MES is not an MES… but something different entirely.

In fact, the term for it does not even exist yet. It is more than what has existed as an MES before.

It might be a manufacturing operating system, a suite of manufacturing apps, MOM, MOS, etc. but the name or acronym is not what is important. For clarity, we'll call it "MES" here.

> *The key differentiator of next-gen MES is the unique value it provides that no other solution before has provided.*

In other words, It is about what it **DOES** and what it **GIVES**. Let's consider next-gen MES through both of these lenses next.

CHAPTER THREE

# What Does a Next-Gen MES Do?

A next-gen MES ...

- Contains low-/no-code authoring capabilities so that non-programmers can configure and use the system
- Solves new business, manufacturing, and process problems that legacy MES systems have historically failed to solve
- Is designed intentionally for the ACTUAL users: operators, scientists, quality managers, MSAT personnel NOT the IT, automation, or programmer personnel
- Moves beyond one site or team to a fully connected web of cross-enterprise teams in manufacturing
- Becomes a MUST have versus a nice to have
- Challenges the way things have traditionally been done in the industry

Let's put these factors into a formula:

**Next-gen MES = Σ (a problem of immense value + a brilliant, performant, purposeful solution + real user joy)**

The true benchmark? A next-gen MES does so much that it becomes a MUST have, versus a nice to have.

CHAPTER FOUR

# What Value Does It Provide?

A next-gen MES...

- Fosters a community of manufacturing and process knowledge
- Connects siloed manufacturing teams across an organization and outside an organization
- Provides instant tech transfer across sites, teams, and the drug lifecycle
- Brings New Product Introduction (NPI) from months to days
- Reduces process/recipe development time from months to days or even hours
- Reduces upgrades and validation times to hours
- Enables predictive or instant batch release
- Empowers and shifts decisions and influence to operators, scientists, MSAT and quality personnel
- Reduces the footprint and total cost of ownership for a user of maintaining such a system

I could go on and on. You might think these statements are just semantics, but they are key to building and innovating a truly pivotal product.

But in a nutshell: when assessing MES options, focus on value.

> *Focusing on the value an MES provides makes it easier to distinguish what's truly "next-gen" and what's merely trending.*

CHAPTER FIVE

# Explaining Through Examples

Now that we've covered what a next-gen MES does and what it gives, let's break it down with some examples.

You might say "Adding AI or analytics into MES" is the same as "building a feature that can predict the future quality of an ongoing batch," but it is entirely different.

The first indicates we should build an agnostic intelligent engine pulling in all data and running complex learning algorithms for anything and everything in the MES. It implies a wholly generic solution that can be applied wherever.

Finding an ROI for something like this is a huge challenge. Taking this approach to innovation might be tempting, but I've seen too many pilots or proof of concept projects start and quickly die to follow suit.

However, if you instead apply the formula, you'll start with the problem to be solved: batch release is time consuming and primarily at the end of manufacturing, causing a lag between its completion and the actual release. This delay gets even longer if something is only caught at the end of the review.

So what could we do to address this?

There are a few steps you could take:

- Build a review by exception interactive live tool
- Flag CPPs, CQAs, and trend off these
- Identify previous golden runs, ok runs, and poor runs and have the system perform a live compare at all times against those runs to predict how good or poor this batch will be
- Provide a run-compare tool to understand and automatically highlight the differences between a good and poor run

When implemented, all of the above have a clear, direct both bottom line and user-impacting ROI, while "Adding AI or analytics into MES" does not.

> *The heart of a next-gen system is solving the high stakes, immensely valuable problems in a way that a user simply cannot live without.*

An MES vendor might make use of AI or analytics tools to achieve solving the problem, of course, but that's just the tip of the iceberg.

Technology is just the means to an end. A truly next-gen MES is grounded in solving real-world problems.

CHAPTER SIX

# What Is Required of a Next-Gen MES?

***All this being said, I won't pretend that next-gen MES is simply only a philosophy.***

I am a product person after all, so I've got features front and center. Which brings me to my next topic: core requirements for an MES to be truly next-generational.

In this chapter, we'll explore 3 key features or specific characteristics that make up a next-gen product and its approach to projects and services.

Based upon my experience, industry, and user research, the following capabilities ladder up to a next-gen MES:

| Product Features | Innovative Processes | Purposeful Technology |
| --- | --- | --- |
| That solve unmet industry needs | That re-envision how MES "is done" | That increases the accessibility & ease of MES |

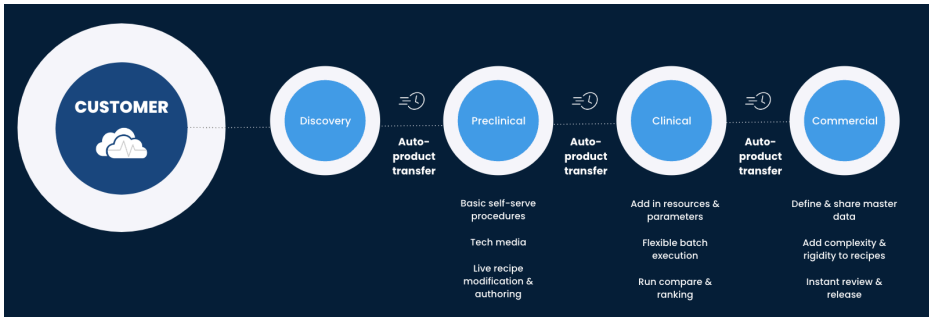
## REQUIREMENT #1: PRODUCT FEATURES

**That exist to solve unmet industry needs**

To serve the needs of process recipes from preclinical through commercial, a truly elastic platform is required.

To achieve this, look for these 3 critical factors:

1. The recipe authoring tool must allow an agile recipe concept where it can easily evolve and gain complexity in iterations across stages and still be usable at every stage.
2. User-generated recipe object templates, parameters, libraries are readily definable.
3. The authoring and execution tools are uniquely designed for and adapt to the user and the environment at that stage (the scientist, the operator, the flexible development lab, the rigid shop floor, etc.)



| Product Feature & Life Sciences Process Opportunities |
| --- |
| Leveling out: End-to-end support across the drug lifecycle from the moment it is discovered to the moment it is shipped |
| Leveling up: Seamless sharing of batch data across enterprise to creating the ability to scale up in house or out with CMO |
| Intuitive and purposeful role focused coverage for all personas |
| New Product Introduction (NPI), lifecycle needs built in not bolt on |
| Repeatable easy configuration (hub & templates) |
| Suitable for smaller sites, preclinical and clinical teams |
| User-generated & defined best practice library of templates |
| Flexibility for ATMP and preclinical to make live process changes |
| Support for changes in QC: inline monitoring, testing, auto-release |
| Decouple the actual batch record from the instructions and orchestration of how the process should be conducted. |
| Support for ballroom, mobile equipment facilities |
| Plug & play recipes that seamlessly connect in equipment activities |
| Flexible weigh & dispense UI activity blocks vs large fixed UX flows |
| The recipe can evolve and gain complexity in iterations across stages and still be usable at every stage. |
| Lays groundwork for lights out facilities and true Biophorum DPMM Adaptive Plant |
| Rises to the challenges set forth in the MES of the Future Manifesto making significant improvements and revolution in those modalities |

## REQUIREMENT #2: INNOVATIVE PROCESSES

**That re-envision how MES "is done"**

Secondly, a truly next-gen MES must have innovative processes in place so that teams are empowered to get the job done right.

*"To become the next-gen MES of the future, software companies will need to focus on providing 'tools/solutions' to critical project execution problems that have an impact on MES project timelines."*

*—Dominique Telfort, Manager, MES Product, Apprentice*

| Opportunities for Innovation in Next-Gen Processes |
| --- |
| Product iterations targeted around industry challenges versus just parts of the application |
| Provides value/ROI in 6-8 weeks not 2 years |
| Seamless, lightweight zero-downtime upgrade process |
| Considers wide range of user market segments (not just big pharma commercial); e.g. small- to medium-sized businesses (SMBs), preclinical, process development labs, and clinical |
| Breaks down the acronyms into simply the manufacturing activities that need to be done. Doesn't get trapped in MES vs LES vs CMMS etc but just provides abilities to meet manufacturing activities for Batches, Materials, Equipment, etc. |
| Supports a user's journey from level 1 to level 5 and beyond in the BioPhorum Digital Plant Maturity Model |
| Re-envisions processes. Doesn't just digitalize existing ones but takes them and modernizes them adding more value |
| Evaluation, Purchase & Initial Deployment is transparent and easy |
| CSA Validation & Risk based methods |
| Provides a licensing and pricing mechanism that scales uniquely to life sciences teams needs as they grow (big or small) |
| Personal account customer success representatives and product feedback implemented constantly |
| Engaging user forums that actually provide strategic direction to the product & build a true community |

## REQUIREMENT #3: PURPOSEFUL TECHNOLOGY

**That increases the accessibility & ease of MES**

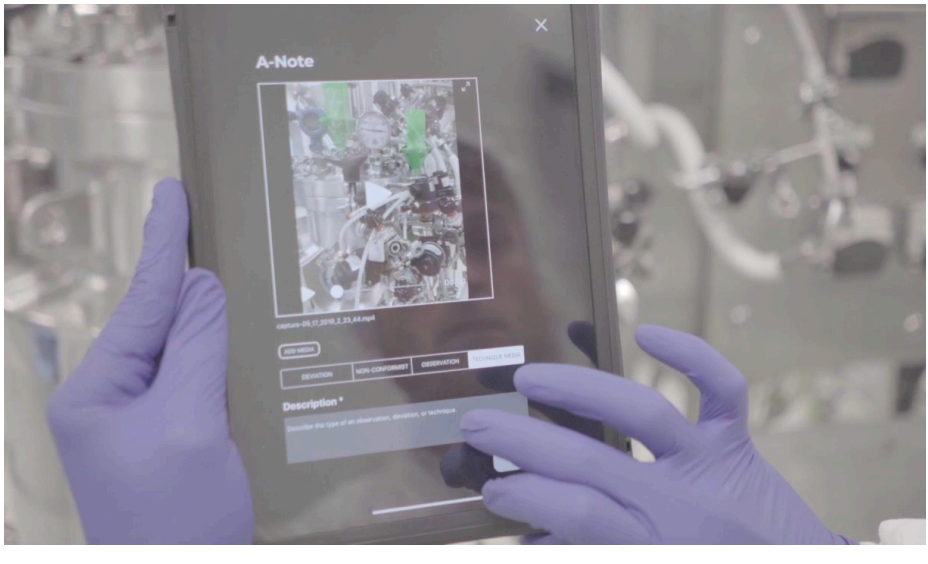
A next-gen MES isn't something that can be bolted on to an existing solution – it's an end-to-end rework of the status quo. And technology is the driving force.

*"Next-gen MES is what you get when you take the best engineers on the planet — the same ones who built the iPhone, who built Uber — and, instead, have them build an MES.*

*This up-leveling in talent allows us to deliver best-in-class software that enables enterprises to increase speed and maximize supply across all of their manufacturing sites."*

*— John Zimmerman, Senior Director, Engineering, Apprentice*

| Technological Advancement Opportunities |
| --- |
| Deployable from edge to enterprise |
| Online user community & knowledge base to share recipes |
| Composable smaller apps or bits of functionality |
| Architecture that drives performance (micro service, pub/sub, event-based approach) |
| Easy to configure & maintain integrations |
| Seamless site to site, enterprise to sites, multi-site and cross enterprise environments |
| Seamless integration with known & loved analytics tools |
| Easy, self-serve data and reporting options |
| Built-in automated testing for software development lifecycle (SDLC) and implementations |



CHAPTER SEVEN

# Your Next-Gen MES Checklist

## How to evaluate if a product is a next-gen MES and if it will remain future-proof

What is the best way to evaluate if a product truly will meet the needs of a next-generation system and how can you feel confident that it won't become or evolve into the same painful legacy solutions on the market? In the following section, we'll provide some suggestions on performing this evaluation.

**Is it a next-gen system now?**

- **Checklist Time:** Use the three sections "Product Features, Innovative Processes, Purposeful Technology" as checklists to evaluate how many line items the CURRENT product feature set, process set, and program set have been achieved

- **Value over Features:** Pay attention to how the vendor articulates the value of the product. Do they highlight a feature showcase? Is it all about "what the product can do"? Or, does it dive into articulating value:
    - Highlighting specific industry problems and challenges it solves and how
    - Evidence of value or ROI of specific problems solved by the product

    - An understanding of how various end to end feature sets result in specific value or addressed need

- **Provide a Personal Challenge:** Identify and share a problem you have that hasn't been solved by legacy MES systems and ask them to respond in detail how they address it. Look for specificity, real demos, ROI evidence and an end-end understanding of your problem

**Will it remain a next-gen system in the future?**

- **Checklist Time:** Use the three sections “Product Features, Innovative Processes, Purposeful Technology” as checklists to evaluate how many line items the vendor has planned for its FUTURE product feature set, process set, and program set

- **Prove Evolution:** Look for proof of iteration of the product, its features and programs over time. Ask the vendor some more qualitative questions:
    - How has your product strategy evolved?
    - Provide examples of how you have pivoted based on industry learnings or trends
    - Provide examples of features that you launched and have iterated on since the first launch and why the iterations were necessary
    - Bonus: see if they are willing to highlight in area where they were originally incorrect and decided to adjust to better serve users

- **Strategic Balance:** Look for balance of the vendor listening to its users addressing their product needs and problems AND the vendor making their own strategic investments that don't come from users. A lasting product is exhibited by releases that have a balance of saying yes to customers, no to customers, meeting industry trend needs, and a little bit of trusting some wild new ideas. Look at release notes, talk to current users, and ask the vendor to demonstrate their approach.

- **Stability Future-Proofing:** Many legacy systems struggle with a mountain of bugs and tech debt that prevent them from innovating. But this doesn't happen overnight. This happens as a result of years of ignoring and not investing in key areas. Ask the vendor about their philosophy and policy on addressing tech debt, security, bugs and performance investments. Then ask them to prove it by highlighting where and in what releases these are being addressed.

- **People & Passion:** A product or company is more than its service or software. The people who build, define and implement the product naturally embed their passion and drive into it. Take time to talk to the people behind the product. Are they passionate about the industry? Are they excited about solving your problems? Do they want to listen and dig into what your goals are? Do they talk in future tense about ideas? Look for passionate people who can see a shared vision with you.

CHAPTER EIGHT

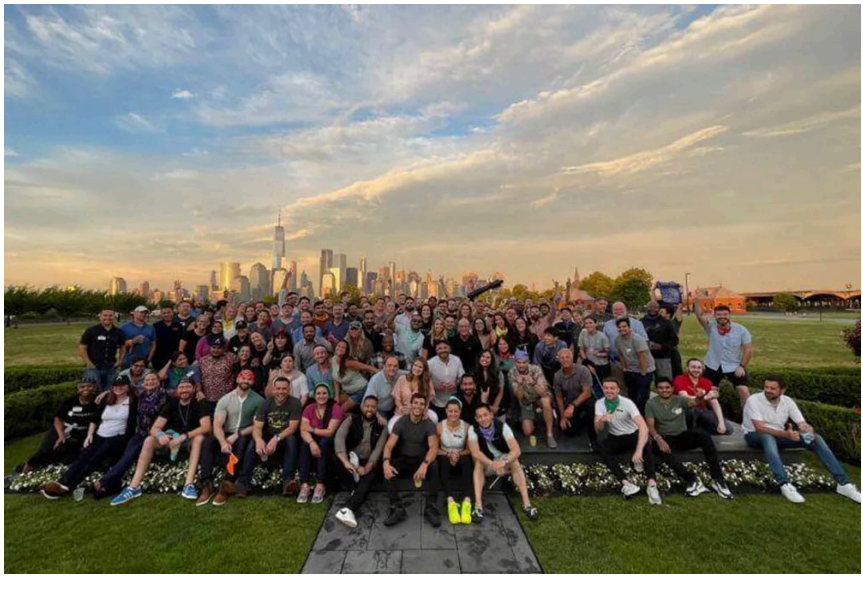
# Closing Thoughts

While achieving all of this is lofty, we believe it is not only possible, but absolutely necessary to move the industry forward, maximize supply, and increase speed to market.

The complete evolution to the definition of a next-gen MES as described above is non-negotiable and is the mission of the team at Apprentice. Our goal is to one day soon, not years from now, achieve every line item above.

To achieve this, these guiding questions light our path forward:

- What aspects above are the highest priority?
- What is missing from the list above?
- What hurdles will we face on this mission?



CHAPTER NINE

# Our Featured Author

We're delighted to feature Emilee Cook as our featured thought leader and author of this piece. When it comes to the future of MES, Emilee is our in-house expert and champion!

Meet Emilee and learn about her career background, interests, and her unique approach to MES in the pharmaceutical space.

## Meet Emilee, our MES enthusiast

- **Who:** Emilee Cook
- **What:** Director of Product
- **When:** 2 years at Apprentice
- **Where:** St. Petersburg, Florida

*"I am an artistic engineer; I take complex technical data and present it in a comprehensible way.*

*Endeavoring to bring human-centered design into engineering throughout product design and new product development, I constantly push to always learn and grow in UX and HCD practices."*

Emilee's an inspiration to our team: both in her deep passion for MES tech, and in how enthusiastically she shares it with others.

## Emilee's background

Emilee Cook leads software development teams at Apprentice, tapping into user data to build better products and improve experiences for manufacturing personnel.

Emilee actively works with pharmaceutical manufacturers to design software that:

- **Accelerates** technology transfer
- **Supports** modular manufacturing
- **Increases** product quality throughout the lifecycle

Promoting women in STEM fields is one of Emilee's top passions; you'll often find her speaking at local universities and teach-in events in her community.


*"Pharma manufacturing saves lives. Working collaboratively to build solutions that get therapies, like the COVID-19 vaccine, to patients faster is something you can't help but resonate with! Manufacturing is a full circle of impact."*

Over her 10 years in the life sciences, Emilee has spent time in R&D on the following endeavors:

- **Producing** biomimetic devices at Draper Laboratory
- **Developing** Syncade solutions for 260+ customer issues
- **Founding** new user-driven product development approaches
- **Crafting** strategies for next-gen pharma solutions at Emerson and now at Apprentice.io

Emilee has recently won Manufacturing Institute's STEP AHEAD Emerging Leader Award for 2021 for these efforts.


While she is an engineer at heart, Emilee is also creative. She's certified in human-centered design and facilitation, and you'll often find her painting and crafting in her free time.

**MEET EMILEE**

## Meet Our Passionate Problem Solvers

From preclinical benchtop to commercial manufacturing, Tempo keeps your global teams connected, empowered, and in sync. Our cloud-based platform gives you the speed and flexibility you need at the clinical stage.

Want to see a next-gen MES in action?

**Request a Demo >**


APPRENTICE

**We're Apprentice, your partner in making medicine.**

Despite incredible therapeutic innovations, the process for manufacturing these life-changing drugs is stuck in the past. Legacy paper-based systems can't hold up to the demands of new therapies or the pressures of new production methods.

Enter Apprentice. We're your trusted partner to bring your operations up to speed with the transformative power of AR tech. Our mission is to simplify your process.