INTRODUCTION

We surveyed a global audience of medical device development leaders about their work.

• What challenges do you encounter in development?
• What tools & methodologies are you using?
• What regulations are you watching?
• What will boost innovation?

Results are in. The data shows an industry in search of steady footing amid market, regulatory, and technological changes.

2019 Key Findings

• Manual processes are limiting productivity.
• Confidence in compliance is down.
• More user & lifecycle visibility is desired.
• Shift toward hybrid Agile.
• Innovation needs investment in R&D.
• All eyes on EU MDR regulations.

Continue reading to explore 2019 medical device development trends, challenges, and innovations.
DEVELOPMENT CHALLENGES

Too Many Meetings, Emails, Status Updates

What’s not adding value to the workday? Meetings, documentation, email, and chasing down project status, say industry professionals.

What 3 activities do you wish you had spent less time on in the past year?

- Unnecessary meetings: 55%
- Documenting/reading documentation: 45%
- Figuring out project status: 41%
- Emailing status updates: 34%
- Tracking down approvals: 27%
- Tracing related items: 26%
- Establishing risk control measures: 22%
- Finding/providing objective evidence: 18%
- Linking code to requirements: 13%

In Your Words

“Getting people to respond to emails.”
“Tracking component status to support product builds.”
“Correcting poor virtual development documentation.”
Manual Development Process Dominates

The use of specialized medical device development tools has increased by 25% since 2016. The majority of teams, however, still manage work with a combination of Word documents and spreadsheets.

According to the survey:

- 65% use Microsoft Word to manage requirements.
- 65% use Microsoft Excel to manage test cases.
- 59% use Microsoft Excel to manage and track issues.

As we can see, teams with a predominantly manual process dedicate time to daily project administrative work.

Good ALM tools can streamline much of the manual processes and free up time for higher priority work.
Collaboration Challenges in Embedded Development

Cross-team collaboration was the number one challenge for development teams building embedded devices. The rise of distributed teams is impacting organizations everywhere. It’s also affecting modern device designers.

Teams developing products with hardware and software often work in disparate systems. This disconnect can stall collaboration among designers, hardware engineers, and coders.

More and more, companies find talent where it lives rather than bring it all together into one office. To work across geographic and time zone boundaries, teams need an accessible system that provides a secure, reliable single source of truth for managing assets, no matter where they sit.

The right tooling — a version control system with proper integrations, for example — can ease many of these asset challenges.

RESOURCE: Why Is Version Control Important?
DESIGN CONTROL CHALLENGES

From user needs to project status, low visibility or knowledge into design control activities is creating challenges.

What’s challenging during the design control phase?

- **28%**
  Lack of clear knowledge around user needs

- **16%**
  Lack of understanding around related defects, documents, requirements

- **15%**
  Developing appropriate risk controls (Hazard Analysis, FMEA, FTA, etc.)

- **15%**
  Developing trace structure

- **15%**
  Little visibility into project status

- **7%**
  Other

- **7%**
  Little visibility into change management

Taking action is difficult when you don’t have all the information.

Responses suggest teams want more context throughout the design control phase. More thorough requirements gathering, with more data on user needs, may reduce unknowns.

The data also highlights opportunities to provide teams with more context around defects, documentation, project status, change management, and more.

Challenges like these can be common for siloed teams using predominantly manual development processes.

**In Your Words**

“Aligning user feedback with the pace of the project to stay on schedule, while also taking time to make sure the product is right.”

“Coworkers are unaware of processes, make up their own, then complain about everything being complicated.”
Doubt Rising in Audit Compliance

There’s an unexpected FDA audit. How confident are you that you’ll pass? Medical device industry leaders in 2019 have less confidence than last year.

How confident are you that you could pass an unannounced FDA audit?

<table>
<thead>
<tr>
<th>Year</th>
<th>Very Confident</th>
<th>Somewhat Confident</th>
<th>Not at all Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>46%</td>
<td>41%</td>
<td>13%</td>
</tr>
<tr>
<td>2019</td>
<td>38%</td>
<td>47%</td>
<td>15%</td>
</tr>
</tbody>
</table>

2019 brought a decline in audit compliance confidence.

Why is confidence down? Lifecycle visibility challenges, noted above during the design control phase, could be contributing. For leaders feeling similarly, solid end-to-end lifecycle traceability can provide assurance.

RESOURCE: How to Improve Confidence Through Traceability
The Proof Is in the Documentation

Proving compliance is never simple. For those involved in the process, three challenges shared top spots: documentation, objective evidence, and risk & hazard analysis.

When you need to prove compliance, what is the most difficult to prove?

- Not involved: 24%
- Documentation: 15%
- Objective evidence: 15%
- Risk & hazard analysis: 14%
- Traceability: 12%
- Design history file: 10%
- Audit trails: 8%
- Other: 2%

Documentation, objective evidence, and risk and hazard analysis top the list.

These results should not surprise anyone with a manual development process. When teams need proof, they have to dive into documentation to make all the necessary connections. Objective evidence, for instance, can be buried (or worse: lost) in spreadsheets. A more formalized documentation & testing process, a robust test management tool, or a combination of both can help greatly.
A surprising majority, 75% of respondents, either aren’t using a coding standard or are unaware if the team is even applying one.

Coding standards help reduce risk by ensuring the development team is conforming to a shared set of industry requirements. Static code analysis can play a pivotal role.
Teams that changed development methodologies in 2018 left Scrum (an Agile method) and Stage-Gate (a Waterfall-based method). A hybrid Agile development process, which combines Agile with more traditional methods, appears to be a settling point — for now. 75% of respondents that switched methods were satisfied with the results.

To meet regulatory & market demands, teams are answering “Agile or Waterfall?” with “Both.”
Resistance to Change, Inadequate Tools
Balk Agile Transition

Numerous teams transitioned to Agile methods in the last year. Not everyone thought it succeeded. Why not? Resistance to change (19%), inadequate tools (19%), and lack of internal knowledge (14%), say respondents.

INDUSTRY FUTURE

Technologies unheard of as recently as a decade ago are finding a place on product roadmaps.

What emerging tech devices are most on your radar in the future?

- Product-specific wearables (Wireless sensors, etc.) 41%
- Smartphones, tablets, or laptops 33%
- None 29%
- Consumer wearables (Smartwatches, fitness, etc.) 24%
- Other 5%

RESOURCE: Transitioning Toward Agile Development in Regulated Industry
Key Drivers of Innovation

What will spur innovation? Industry leaders believe the answer lies in simplified regulations, unified standards, and more investment in R&D.

What would contribute most to product innovation?

<table>
<thead>
<tr>
<th>Contribution</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Simplified regulations</td>
<td>29%</td>
</tr>
<tr>
<td>Unified int’l standards</td>
<td>21%</td>
</tr>
<tr>
<td>Investment in R&amp;D</td>
<td>20%</td>
</tr>
<tr>
<td>Better tech &amp; tools</td>
<td>11%</td>
</tr>
<tr>
<td>More funding options</td>
<td>9%</td>
</tr>
<tr>
<td>More industry dialogue</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
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Simpler Standards & Regulations — Down From 2018

It appears some progress has been made in improving innovation despite the overhead of industry standards and regulations.

Is innovation bound by regulations & standards?

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>57%</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2019</td>
<td>49%</td>
<td>Yes</td>
<td>No</td>
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</table>
Innovation Demands More R&D

Today’s technological landscape offers opportunities to capitalize on innovation. But incorporating these innovations into design requires more investment in R&D. A majority are either currently working on or planning to include emerging tech in product design.

Have connected devices (IoT) impacted your product design?

- 42% Not in plans
- 28% Working on now/another team is working on now
- 30% Including in plans

Have AI and/or machine learning impacted your product design?

- 41% Not in plans
- 29% Including in plans
- 30% Working on now/another team is working on now
Regulations on the Radar

What regulations are you most concerned with in the near future?

- European Union Medical Device Regulation (EU MDR) 49%
- FDA regulations (e.g. 21 CFR) 41%
- ISO 13485:2016 29%
- Revisions to ISO 14971 20%
- Not concerned 12%
- I don't know 10%
- IEC 62304 9%
- Other 2%

It’s no surprise. Many are watching the European Union Medical Device Regulations (MDR) scheduled to take effect on May 25, 2020.

FDA regulations are second. After that, developers are concerned with ISO 13455:2016 (for quality management systems). They’re also watching revisions to ISO 14971, which requires a well-documented narrative of the product lifecycle.

What else? Write in responses included:

- Medical Device Single Audit Program (MDSAP).
- FDA Cybersecurity Regulations (draft currently available for review).
- FDA Section 508 (for formatting requirements documents in Microsoft Office).

RESOURCE: How One Device Developer Achieved 21 CFR Part 11 Compliance
WHAT’S NEXT?

Will hybrid Agile development continue to be the preferred process for medical device developers? Will device developers address manual processes? How exactly will the increase in emerging technologies impact how teams collaborate?

All good questions. We plan to investigate them for 2020.

How Helix ALM Helps

Helix ALM helps medical device developers manage projects, prove compliance, and improve productivity. Learn more.

WATCH DEMO

ABOUT THE SURVEY

Perforce surveyed 267 medical device professionals in February 2019. Participants represented a wide range of experience. From industry veterans with 10+ years of experience in the upper tiers of management to development professionals with under a year of experience. Survey respondents also represented a diverse range of device types (hardware, software, both), and classes (I, II, III, IV, De Novo).