Custom Agile-based Project Management for EU MDR/IVDR Transition

Darshan Vora, Quality Manager, Tata Elxsi
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ABSTRACT

The European Union Parliament released Medical Device Regulation (MDR 2017/745) and In-Vitro Diagnostic Device Regulation (IVDR 2017/746) to govern the manufacturing and distribution of medical devices and in-vitro diagnostic devices, respectively, in the markets under European Union. All the CE certificates as per Medical Device Directive (MDD), Active Medical Device Directive (AMDD) and In-Vitro Diagnostic Device Directive (IVDD) will cease to be valid after the mandated deadline unless companies proactively transition to the newer regulations. The impact of this change is felt across the industry, medium to large-sized companies are grappling with challenges associated with the transition.

Project management is one of the critical success factors for driving a transition of such a large scale. While various project management methodologies can be utilized to manage the gap assessment and remediation activities for multiple functions, this whitepaper discusses the use of agile-based project management for executing high-volume remediation.
INTRODUCTION

All the marketed medical device products which are compliant with MDD and AMDD are required to migrate to EU MDR. On the other hand, in-vitro diagnostic devices compliant to IVDD need to now comply with EU IVDR requirements. The most important aspect of the entire exercise is to have all the commercially available products comply with the new requirements before the mandated deadline to avoid financial implications on the companies’ commercial interest in the EU region.

Figure 1: MDR & IVDR compliance timeline
REGULATORY ENVIRONMENT TRANSITION

The MDD to MDR transition has mandated the assessment of the entire product portfolio under the new rule of stringent risk assessment including periodic and streamlined market feedback presented by the PMS (Post-market surveillance) and PMCF (Post-market clinical follow-up). This typically involves identifying the gaps, performing required design, testing, process changes and finally rectifying all the affected artifacts. Post transition all the revised technical files have to be recertified by the notified bodies for them to be continued in the market.

The Medium and large-size organizations can typically have hundreds of medical systems spanning across thousands of individual medical products. The challenge lies in the fact that all these products have to be individually transitioned within the timeframe of 3-4 years. This transition burden on the industry has stalled the regular R&D activities and the focus has shifted to containing the cost of quality.

On a technical level, the crux of MDR is on proving the safety and efficacy of the product. This can only be achieved by providing testing proofs that the risk management process has been strictly adhered to, biological and clinical evaluation and corresponding tests have been adequately performed, market feedback in terms of proactive surveillance and handling complaints has been adequately integrated into periodic review product safety post-launch of the product. In the best-case scenario, a slight modification in all the above aspects should be enough for a product to successfully transition to MDR albeit if the post-market surveillance process is strong. On the flip side, the entire risk analysis, performance testing, clinical evaluation needs to be repeated and post-market surveillance processes need to be set-up from scratch.

Considering a mediocre case, the efforts for the entire transition can be broadly estimated by multiplying the efforts of changing a single technical file and performing similar tests for all the products under a company’s portfolio which usually runs in thousands.
DOING THINGS THE AGILE WAY

Agile as a methodology is suitable for churning out short and periodic outputs, which in turn help in overcoming the challenges of a large volume of work made up of repeatable tasks. Thereby, it seems logical to explore agile methodology to resolve multi-product (large volume) technical file remediation (repeatable tasks).

Considering the nature of the program, there are several pre-requisites to be fulfilled before scrum is implemented for EU MDR/IVDR projects, i.e. tailoring scrum to suit the transition program requirements.

The most critical factors which need to be tailored for MDR/IVDR activities as they cannot be as is implemented like any software development. The following four focus areas have high impact on successful program execution using Agile methodology.

- Agile Principles
- Scrum framework
- Estimation of sprints
- Key Performance Indicators

Redefining Agile Principles

There are 12 agile principles that focus on the core aspects and foundation of any program. These principles mainly concentrate on collaboration, continuous delivery of working software and continuous improvements through learnings and retrospections.

These principles need to be tailored for EU MDR/IVDR transition since there is no working software delivery at regular intervals which is also a measure for success of the project. Each principle is analyzed and tailored for transition requirements while keeping the core requirements intact.

<table>
<thead>
<tr>
<th>Continuous Delivery: Satisfy the Notified Body, through early and continuous delivery in small packages</th>
<th>Flexibility: Adopt changing priorities and scope of MDR compliance, to get aligned with Client business needs</th>
<th>Shorter Timeframe: Deliver submission ready Tech Files at regular frequently, monthly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrospective: At regular intervals, the team to look back and find out how to become more effective, and adjusts its behaviour accordingly</td>
<td>MDR Program Management Objective Project team and stakeholders interaction While following processes and tools Deliver Submission Ready Tech Files to RA than waiting for comprehensive system Tata Elxsi and Client collaboration beyond contract and scope Responding to changing scenarios over following a fixed plan</td>
<td>Engage Stakeholders: Involve Business, product, RA, manufacturing, packaging and labelling team in decision making process and work together daily, throughout the project</td>
</tr>
<tr>
<td>Evolve: Keep moving than waiting for defining a perfect approach. Let the team be self-organizing and emerge with best practices and optimized process</td>
<td></td>
<td>Team: Build projects around motivated individuals, give them the environment and support they need, and trust them</td>
</tr>
<tr>
<td>Deliver Value vs. Volume: Focus on priorities aligned to regulation deadline and business need than volume of systems and articles covered</td>
<td></td>
<td>Communication: Face-to-face conversation, the most efficient and effective method of conveying information</td>
</tr>
<tr>
<td>Excellence: Enhances agility and achieve first time right by continuous attention to detailed Gap analysis, optimum but appropriate implementation</td>
<td>Common Goal: Customer and TE teams should be able to maintain a constant pace throughout program</td>
<td>Outcome Vs. Output: Number of Tech Files ready for submission to Notified Body will be the primary measure of progress</td>
</tr>
</tbody>
</table>

Reference: Agile Manifesto of Software Development

Figure 2: Re-defining agile principles for EU MDR/IVDR projects
Scrum Framework for MDR

The standard scrum framework is tailored for MDR program which involves all the stakeholders both from Tata Elxsi and client-side (see figure 3). The RA team acts as a product owner in this kind of program, having the final authority to approve the deliverables (remediated files). Product backlog grooming is done on a monthly basis along with a change control board (CCB) meeting which involves prioritization of work, resolution of dependencies and outlining of scope for the next sprint.

Once the backlog is finalized and mutually agreed upon, the sprint execution remains the same as standard activity; except in the case of software development, the sprint review is expected to have a demonstrable software, a key measure for the success of the sprint. However, in the case of MDR this principle of Agile is slightly tailored where the output is submitted to RA team for approval. For any comments or feedback received from the RA team, product backlog is updated and based on the priority the work is considered in further sprint planning.

Estimating the sprints:

In typical software development, estimates are the basis for success or failure of projects but the estimations in agile works exactly opposite to the conventional estimations. It is relatively easier to estimate a feature or requirement or even set of features for any application or software under development. The same becomes challenging for a remediation project, and this is where one of the critical agile principles is defeated.

In scrum, sprints of equal time duration are defined and user stories are the features, which are estimated considering knowns, uncertainties and complexity. This is how the relative estimation is done for each user story. User stories with higher story points are generally considered as ‘epic’ and as a
guideline, story points higher than 20 story points are required to be further broken down into user stories. Estimation improves the project time or sprint on sprint as the team is able to get a hold on velocity and this further improves the overall planning of the program.

The similar user story based estimation method is taken up for MDR activities, however, this is one of the key challenges. Estimation for software sprints cannot be directly translated to estimation for the articles or instruments. However, to keep the framework intact user stories are defined and user story points are associated with each user story. User stories are defined right from gap assessment, technical re-work or remediation, review and corrections, and RA feedback incorporation.

The set of user stories remain common for any article except the change or variance in complexity from article to article. The user story points associated are based on the relative complexity of the article and the kind of effort needed to complete the gap assessment or technical remediation. These story points are generally higher than user stories in software development projects, and this needs to be taken as an exception for such programs.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Delivery Batch</th>
<th>Delivery Month</th>
<th>System Name</th>
<th>Number Of Articles</th>
<th>User Stories</th>
<th>Story Points</th>
<th>Total Story Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Month-1</td>
<td>System -1</td>
<td>68</td>
<td>Preparation &amp; RMF Grouping Confirmation, RMF-1 Gap analysis (GSPR), RMF-1 Technical Doc Update, RMF-1 Product Team Review and Rework, RMF-1 RA approval</td>
<td>88</td>
<td>680</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>Month-1</td>
<td>System -2</td>
<td>166</td>
<td>Preparation &amp; RMF Grouping Confirmation, RMF-1 Gap analysis (GSPR), RMF-1 Technical Doc Update, RMF-1 Product Team Review and Rework, RMF-1 RA approval</td>
<td>216</td>
<td>1660</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>Month-2</td>
<td>System-3</td>
<td>100</td>
<td>Preparation &amp; RMF Grouping Confirmation, RMF-1 Gap analysis (GSPR), RMF-1 Technical Doc Update, RMF-1 Product Team Review and Rework, RMF-1 RA approval</td>
<td>200</td>
<td>1200</td>
</tr>
</tbody>
</table>

Table 1: Sample scrum backlog for MDR/IVDR projects

As shown in table 1, a typical backlog for MDR program would include user stories and story points associated with each user story.
Key Performance Indicators (KPI’s)

KPI’s are the way to measure the progress of any program and this gives insights into whether the program is going in the right direction or team needs support to remove the impediments. KPI’s have to be program specific, which help the team to have forecast and visibility of key parameters driving the success or failure of sprint or program. This could be easily achieved by setting up the entire sprint framework (product backlog, sprint backlog, epics, user stories, task, etc.) into tools. As teams track the day to day activities for a given sprint these KPIs are derived and monitored as part of daily standup meetings to take in-process metrics based actions and corrections. This KPI’s further get reviewed as part of the sprint restrospection meeting along with stakeholders. This helps to plan or re-prioritize the next sprints.

Below figure gives a sample KPI snapshot which can be further tailored based on the activities involved in MDR or IVDR programs.

*Figure 4: Sample KPI’s for MDR/IVDR projects*
CONCLUSION

Considering the quantum of work chalked out for the medical device and diagnostic companies, project management needs to be addressed adequately to ensure a smooth transition. The scrum methodology for remediation activities is feasible if there is a good amount of pre-planning done in terms of understanding the overall systems and articles involved. Also, estimation is a critical factor that needs to be tailored for such activities and device custom mechanisms for story point estimation, which gives clear visibility of the progress of the overall program.

This approach has helped in achieving the higher throughput of deliverables and aided in getting early feedback on the output delivered to the customer, which otherwise would be pending up until the last stage before making submissions to the Notified Bodies and eventually would pose a high risk to the program.

Following the agile principles ensures close collaboration between key stakeholders as any potential blockers or impediments are addressed early and regularly.
ABOUT TATA ELXSI

Tata Elxsi is a design company that blends technology, creativity, and engineering to help customers transform ideas into world-class products and solutions. Tata Elxsi has extensive experience in helping companies launch medical imaging, in-vitro diagnostic, patient monitoring, therapeutic and surgical devices in developed and emerging markets.

Tata Elxsi has been instrumental in helping global companies transition from MDD, AIMDD, and IVDD to EU MDR and IVDR. Two years into transition, Tata Elxsi’s custom agile-based project management for the healthcare industry is benefiting medical device manufacturers to handle high volume implementation and unpredictability associated with the transition.
REFERENCES

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