

Make it Better

A risk-based approach to design for manufacture and assembly allows the manufacturer to have greater control over each stage in the production process, which brings with it the assurance that a process will yield its expected return

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Every designer, manufacturer and assembler – no matter the product or sector – wants certainty. Clearly, manufacturers want assurance that the product they have invested time, energy and money into conceiving and designing is going to make it through manufacturing and assembling to market, without added costs or last minute delays. Once the product reaches the market, they want a lean, reliable and safe production process without problems. They are not gamblers and they don't like risks, especially in the healthcare and life science industries.

These concerns aren't new. In the late 1960s and 1970s, Geoff Boothroyd began to wrestle with such problems and began his analysis of the time required to manually assemble a product. By the early 1980s he was working with Peter Dewhurst on computerised techniques for reducing the cost and time of assembly (1). Design for Assembly (DFA), as the technique was known, swiftly became the way forward in manufacturing to streamline production, and reduce both the time it took to make a product and the relating cost.

Central to Boothroyd and Dewhurst's work is the idea that a product can be assembled more rapidly, more reliably and, as a result, more profitably if it comprises as few components as possible. This is a good approach that has served the industry well for the last 30 years, and will continue to be a

reliable technique for all those wishing to improve any production line.

However, while understanding the cost and time involved for each manufacturing and assembly step is relevant, the use of risk as the basis of evaluation of each step can be a sharper and more relevant tool, especially where quality and reliability are of paramount importance. To avoid confusion, we are not advocating a solely risk-based approach to design for manufacture and assembly (DFMA). Instead, the whole process needs to look at multiple factors such as cost, availability of supply, time to setup, resource availability, and so on. We would then argue that risk analysis should play a more integral role.

development project. It is wholly appropriate to proceed with only part of the process in place – and it will provide maximum effect if it is carried out as early as the concept selection phase.

What's the Risk?

In recent decades the world has become more aware of the concept of risk. An ever keener interest in avoiding harm, failure or litigation has meant that industry has become better at analysing and understanding it. Now, rather than just fearing the negative results of risk, and preparing to cope with the consequences, we can use risk as a way of steering us towards a more positive outcome where better and safer products are easier to produce.

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A key point to remember is that carrying out a DFMA should not be treated as a box ticking exercise within the sign-off process. It should be carried out at intervals throughout the course of the

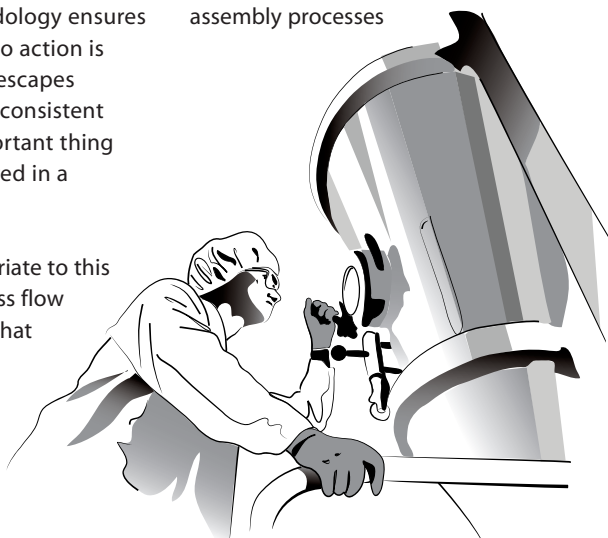
The risk being discussed here, however, isn't about a deferred risk to a user's safety (either patient or healthcare professional), but the consideration of what stands in the way of the process

that creates that product from operating perfectly. In the context of DFMA, risk is anything that hinders an ability to set up, validate and maintain a robust and capable process. A capable process is one that will effectively and efficiently deliver a component or product that meets the design specification and by a margin that is able to deliver sustained performance and quality. A capable process therefore guarantees a high yield of products that meet the required specifications, and delivers them in an efficient way.

Step it Up

Any manufacturing or assembly process can be sub-divided into small, discrete steps. In each step there may be a number of actions, such as machining a surface, picking up a part, placing it on a sub-assembly, moving it somewhere or joining it to something. With each such action there is an associated risk of the action not being completed successfully. This might be to do with unrealistically tight manufacturing tolerances, a component's fragility and the ease with which it can be damaged, or with the difficulty associated in making parts accurately or positioning them correctly. These are just a couple of examples. In terms of practical implementation, common to all successful approaches is structure and discipline. Good methodology ensures that no step is missed, no action is overlooked and no risk escapes consideration. Having a consistent system is the most important thing so that all steps are scored in a comparable way.

The toolkit most appropriate to this activity includes a process flow chart. This is a vital tool that helps the manufacture and assembly to be broken into the vital steps and, in turn, creating the steps



dictates the nature of the flowchart. Secondly, a risk analysis template is needed. This is usually an electronic spreadsheet into which the steps of manufacture and assembly, already identified on the flowchart, can be laid out chronologically. Collectively, the toolkit provides the means to crystallise the information that will enable the risk associated with the entire project to be understood and communicated.

When the steps have been identified, using the toolkit ensures all relevant questions are asked of each step, and so an assessment of risk level can be determined in a uniform way. Risk levels could be a number between 1 and 10, or 'low', 'medium' and 'high', or any other scales that might be preferred. However, it is important that these levels are mapped against 'acceptable', 'as low as reasonably practicable (ALARP)' or 'not acceptable' – which correspond comfortably with a traffic light coding of green, amber and red.

These values should be recorded in the analysis template and against each step on the flowchart. Finally, applying the traffic-light colours to the exploded assembly diagram enables rapid identification of where the high risk 'hot spots' of a design can be found. In approaching manufacturing and assembly processes

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Hot Tips for Design for Manufacture

- Design using tolerances that are appropriate for the material, the geometry and the manufacturing process
- Wherever possible, avoid dimensioning across split lines
- Avoid the need for multiple/excessive set-ups
- Avoid slender unsupported regions which are prone to distortion
- Avoid selecting materials where properties often vary

in this way, the quality of the finished product will be higher and more likely to meet the design specification, its reliability will be improved and production targets are more likely to be met.

The More Brains the Better

Getting through this process successfully ideally needs the

brainpower of more than one person. The views of all those with relevant expertise are worth having as they can give a better analysis of the risks associated with any production step, and how to remedy it. This peer review should play an integral part of the development process.

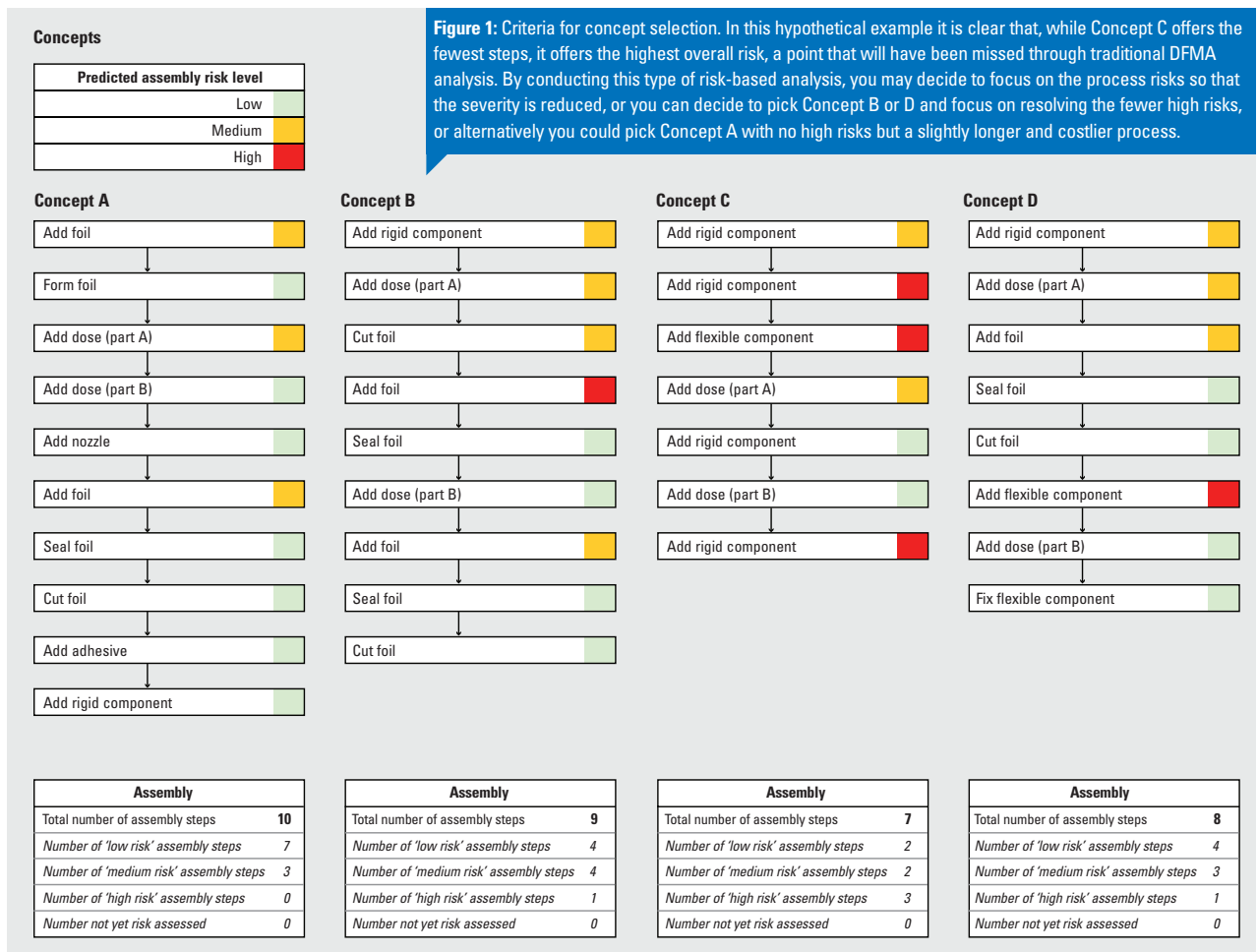
As in our case, the review team will comprise representatives from moulding and tooling firms, manufacturers and contract assemblers, designers and engineers of all relevant disciplines, at the appropriate stages of review. Without their contributions, the DFMA assessment is vulnerable to being rejected at a stage when it would be costly to alter a design and there would, ironically, be a risk that the DFMA assessment would be insufficient. It's only with

their commitment that the review has maximum value.

A final step in the process is to represent the assessment of risk in a way that it can be used intelligently. Clearly, the analysis of each step between the manufacture of the first sub-component and the product being packaged is useful to building confidence that the product can be made, and that it will be known to be safe, reliable and manufactured in the most efficient way. It is essential to be able to communicate this confidence, or a lack of it, without asking everyone to repeat the assessment for themselves.

Ultimately, there will be someone who has to make a decision to sign-off on a design and commit what began as a concept to production. It is very possible that the analysis is carried out, in parallel, for a variety of such concepts with the victor being selected for

Figure 1: Criteria for concept selection. In this hypothetical example it is clear that, while Concept C offers the fewest steps, it offers the highest overall risk, a point that will have been missed through traditional DFMA analysis. By conducting this type of risk-based analysis, you may decide to focus on the process risks so that the severity is reduced, or you can decide to pick Concept B or D and focus on resolving the fewer high risks, or alternatively you could pick Concept A with no high risks but a slightly longer and costlier process.



Hot Tips for Design for Assembly

- Design for easy access and/or unrestricted vision
- Make the number of parts in an assembly as small as reasonably possible
- Design for part placing (easy to align, self-sustained orientation, that eliminates some of the need for accurate positioning by operator or machine) and straight line assembly
- Wherever possible, avoid screws and fasteners. If unavoidable, minimise the number of fastener types used
- Utilise 'Poke Yoke' techniques wherever possible – for example, ensuring that components cannot physically be assembled the wrong way round, as well as using coloured components

production (see Figure 1). To make the correct selection in a simple way, we need to present the work of the DFMA risk analysis as a top level summary.

This summary needs only to report that a design carries a risk level that is acceptable, or unacceptable. Ideally, it will also give information for both manufacture and assembly, recording the total number of steps within each area and the number of steps falling into the low, medium or high risk categories. A summary can also comment on the probability of reducing the risk further and suggest the likelihood of the design being able to cross the threshold into acceptability.

Conclusion

When Boothroyd and Dewhurst began their work in the 1980s the objective was to improve quality, reliability and profitability through improvement of the assembly process. Simplification and reduction of the number of components was the focus. The objective is still largely to produce better products that can be manufactured easily with high production yields. Particularly in the life science sector, risk is a powerful way of scrutinising the steps that lead to the realisation of this objective.

Implementing such a system cannot be done without it becoming a cultural norm within the company reviewing the design. The approach requires discipline and the support of senior management. However, with that support and cultural acceptance, DFMA is a certain route to product success and a far cry from a risky gamble.

Reference

1. Boothroyd G, Dewhurst P and Knight W, *Product Design for Manufacture and Assembly*, 3rd Edition, CRC Press, 2010

About the Authors



Stuart Kay heads up the Electro-Mechanical Engineering group at Team Consulting Ltd, which focuses on designing and developing highly complex and integrated medical systems. Stuart contributes strong skills in technical leadership, design and process engineering and detailed engineering analysis, and is known for the generation of inventive, capable and reliable engineering solutions. Email: stuart.kay@team-consulting.com



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