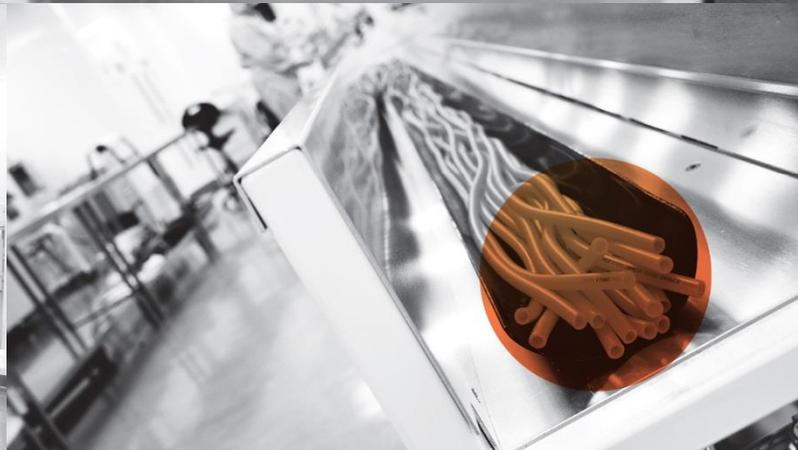


## Injection Moulding – Problem Solving for Medical Device Manufacturing



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***In the design and manufacture of components for medical devices, getting the tooling and injection moulding processes right is critical to the success of the device once it is launched to the market. Nicole Sutton, a member of the Engineering & Product Development team at Mi3, details the steps involved in identifying potential problems with the injection moulding process and how to solve them.***

Injection moulding processes have a glossary of defects and the number of variables can often confuse and cloud an obvious solution. Equipped with a systematic approach and the correct problem-solving tools, you can methodically rule-out possible causes and arrive at the actual root cause.

8D, DMAIC, PDCA and Kaizen are different methodologies used to put structure into a problem-solving exercise and whilst they utilise different tools, they all have the same principles.



### **Watch**

Watch the process and go to Gemba.

Gemba is a Japanese term coined from the development of lean manufacturing practices meaning, 'the place where the value is created' i.e. go and watch the work being done. It helps you to understand the work stream and identify waste (or problems) in a way that reading a work instruction or procedure cannot.

When dealing with injection moulding issues you need to watch the process, understand the, 'hidden factory' and speak to the people running, managing and maintaining the equipment. The aim is to get a firsthand account of the problem and events leading up to the issue right down to the temperature of the room or stress levels of the day.

*Could a step have been missed due a sudden rush to get product out? Could the components be impacted by a colder-than-normal room?*

### **Investigate**

Investigate the problem in its entirety.

Before you jump into solving the problem, take a step back, look at all the data and ask:

*"What else is impacted; other shifts, machines, components?"*

Too often is a problem misidentified leading to ineffective actions, which means the problem crops up time and time again.

With a new-found understanding of the process, events and scope of the problem, gather a cross-functional team and begin to brainstorm possible causes. Ensure there's a representative from each department involved in the workstream; each person will know the intricate details of their part in the process. This may include Production, Maintenance and Quality team members.

Tools such as Ishikawa or 5 whys can be used to map out all possible causes (even the seemingly unlikely). Begin by confirming any assumptions, then systematically rule out each cause with a specific test, beginning with the most basic.

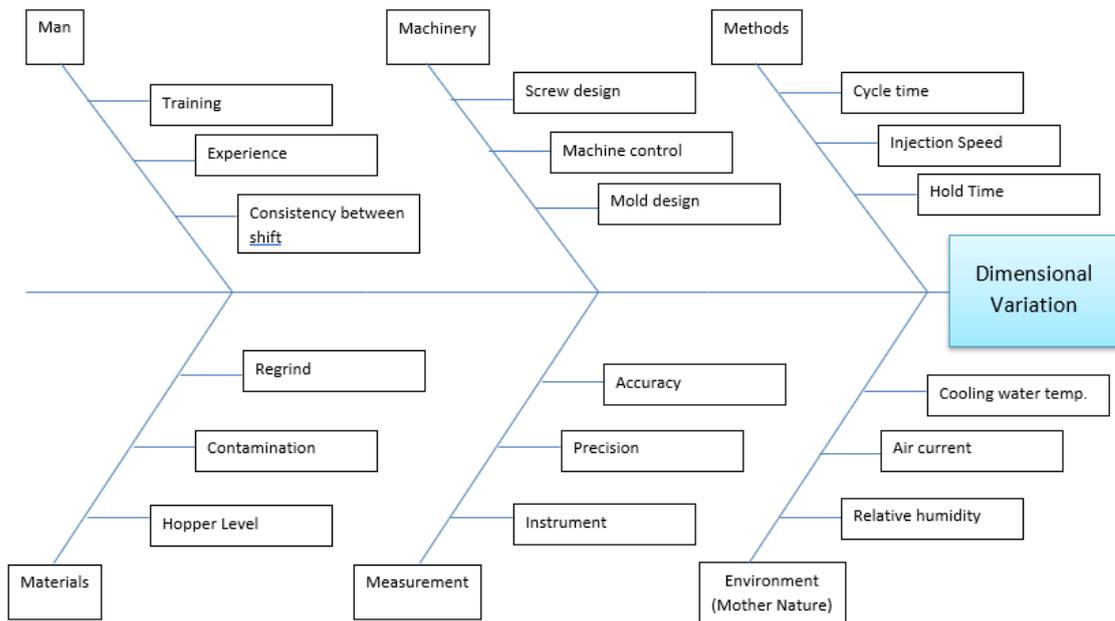


Figure 1. Example of Ishikawa diagram mapping potential causes of dimensional variation in an injection moulding process

### Action

Depending on the fault observed you may need to trial different parameters either to find the cause of the fault and/or find the optimal settings to correct the fault.

This can be approached by either iteratively changing parameters to help attribute the cause to a single factor or completing a Design of Experiment (DOE).

A DOE is a statistically planned set of trials which tests the effect of multiple factors at once. Unlike DOE, iterative testing will not consider the interaction and the effect that each parameter has on the other and can therefore cloud the bigger picture.

With the data at your fingertips, you can attribute a root cause and determine an appropriate action to fix the problem and prevent recurrence. In some cases, preventing recurrence is just not possible and a system needs to be put in place to monitor,

### Conclusion

Mi3 are well-versed in the manufacture and supply of injection moulded plastic components, however, even established processes can go awry from time-to-time. With a cross-functional team of experienced process technicians and engineers, IM problem-solving is efficient and managed expertly so as not to disrupt the supply chain. In addition to offering a dependable supply of injection moulded plastic components, Mi3 can also help design, develop and implement new injection moulding tools to meet your - and your customer's - requirements.

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manage and reduce the impact of any future recurrence.

This may take the form of increasing the frequency or scope of preventative maintenance.

### Review

Review the actions implemented to ensure you've achieved what you set out to *i.e. has the problem recurred or has the problem been reduced by X?*

To anticipate future problems, day-to-day IM performance should also be reviewed. Introducing a simple logbook to the IM team to note any quirks or kinks of the equipment or process will provide data for trending. By reviewing this data, you can identify any minor hiccups early and anticipate a larger problem. After all, intervention and prevention are often cheaper than recovery.



**About the Author:**

*Nicole is a Product Development Engineer working as part of the Engineering & Product Development team to design, develop and realise new products as well as maintain and improve existing products and manufacturing processes. With four years of experience in the medical device manufacturing industry, Nicole has been involved in a number of projects including improvements to product design and quality and process efficiency improvements.*

**About Mi3:**

*Mi3 are the experts in designing, developing and manufacturing end-to-end advanced medical and surgical solutions – providing specialist knowledge in high precision injection moulding, thermoplastic engineering, tubing systems, and regulatory compliance.*

*We take your product ideas from consultation to concept to production, and work alongside you to bring medical innovations to life. Visit our website at [www.mi-3.co.uk](http://www.mi-3.co.uk) to learn more about our packaging, product design and development, and manufacturing services or contact us directly by clicking [here](#) to discuss your requirements.*