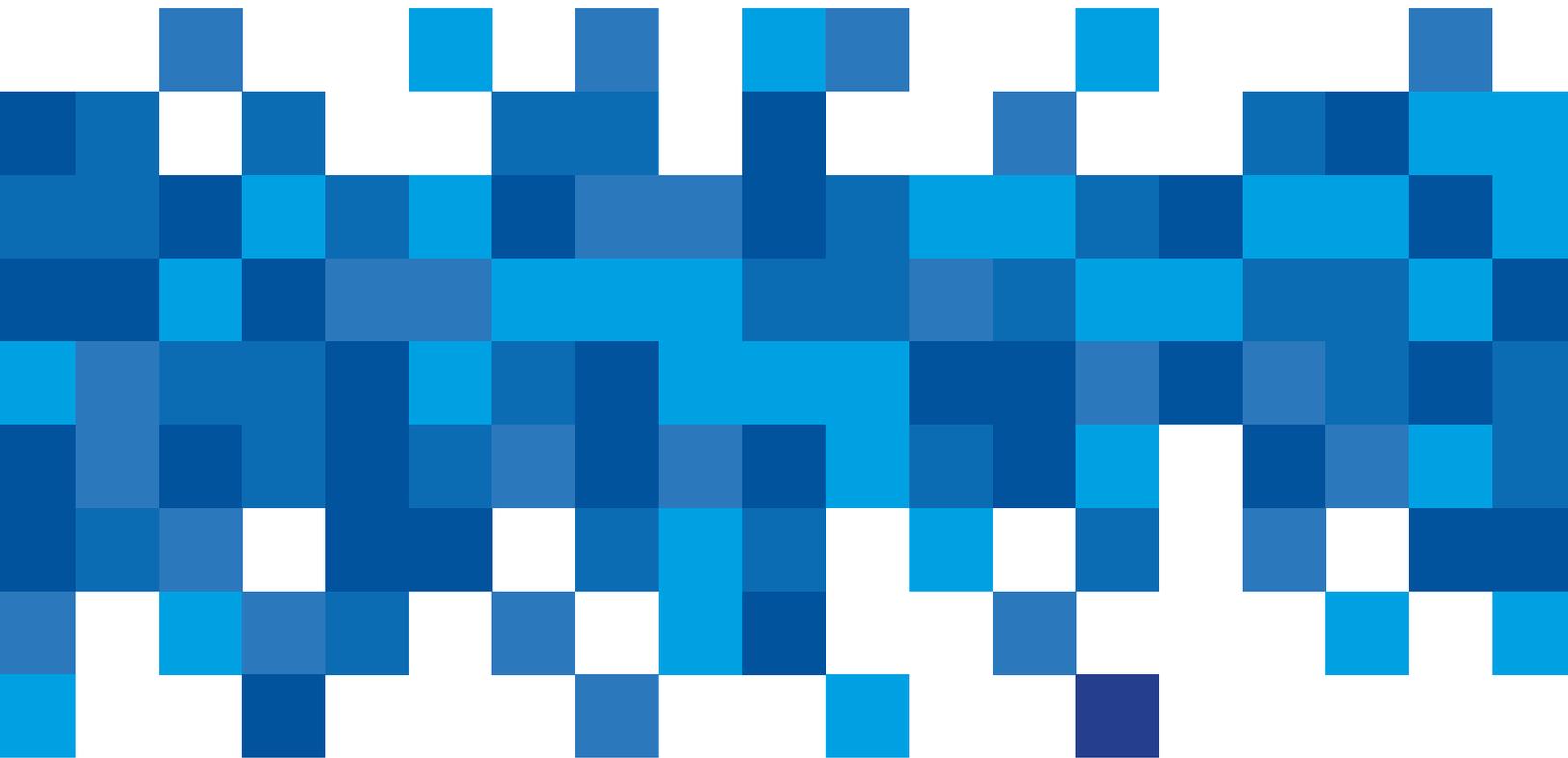


Scientific Molding: The Key to Consistency



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The practice of scientific molding is not new to our industry. It is a proven method that allows molders to gain complete control over the injection molding process and create a precise, repeatable process, which ensures consistency and the highest quality product. To fully control the end result, scientific molders must focus on the chemistry and makeup of the materials used in the molding process, rather than the machines used to create the components. Scientific molders are able to give their clients the assurance that discipline is applied to each stage of the molding process, and that they are committed to using an established set of principles to guide their workflows. This is particularly important for medical products that have stringent requirements for process documentation and validation.

Scientific molding helps remove the guesswork when developing new products. When a team leverages the principles of scientific molding, they use the same methods to kick off all new work. You can be certain that regardless of who takes the lead on a new molding project, the same methodologies are used and that the same practices are repeated on day 1 and again on day 100 of a run.

Non-scientific molders tend to rely on the machines, assuming that programmed processes are reliable and consistent. This is not always the case – even though a computer is set a certain way, there is no guarantee that the outcome will be reliable. In scientific molding, molders review and test the finished product from each machine – along with the machines themselves – on a regular basis to ensure that the results are ideal.

How Does Scientific Molding Help?

Scientific molding helps reduce waste by preventing errors and optimizing the molding process on the front end of the development cycle. In addition, the internal team can limit the amount of time they spend putting out fires and solving problems – they can be proactive instead of reactive. Molders think critically about each product and process, and gather all available information to make ongoing assessments. This is a stark contrast to molders who rely on programmed settings and address issues only after they arise. In this scenario, the molder spends time trying to determine the cause of the problem after the fact, rather than preventing issues from the outset.

Working with a scientific molder offers many benefits beyond consistency and quality. The tenets of scientific molding satisfy validation requirements for Operation Qualification (OQ) and Production Qualification (PQ). These require a molder to demonstrate how their processes are developed and that it is repeatable. These elements are stringently documented as part of the product development and testing process, making the information readily available for customers who require it.

Best Practices in Scientific Molding

Becoming a scientific molder requires a long-term commitment to education and full dedication to the principles. The entire organization must adhere to the established processes and be disciplined in their work. When assessing a scientific molder, there are several key areas that should be reviewed. The following practices are essential to get the results you seek.

Training

Many organizations choose to send several engineers to off-site training programs to learn the fundamentals of scientific molding. Once trained, these engineers are responsible for teaching the principles to existing and new staff. This is not limited to material handlers and machine operators – staff in other departments, including engineering, tooling, quality and maintenance, should also be trained in scientific molding. Anyone who is involved in the project needs to have a strong foundation in the principles so that they can help reinforce consistency.

A scientific molder makes adjustments to machine settings based on test results.



Scientific molding requires focused training that not only covers technical specifications and materials, but also teaches molders to think critically about product design and process improvements. Typically, the training process takes around three months and includes a combination of classroom and on-the-floor sessions.

Topics include:

- Basic chemistry and material fundamentals
- Machine functionality and controls
- Process review and development
- Safety
- Experiments
- Optimization and troubleshooting
- Part design and mold design

Your scientific molder should conduct training annually, with individual reviews happening periodically throughout the year. These one-on-one sessions help maintain proficiency and enable engineers to conduct guided sessions that monitor progress on an entire job from start to finish. Even though the principles of scientific molding are well defined and unlikely to change, it is important to continually refresh and reinforce the training to ensure that team members are continuing to adhere to them.

Testing

Scientific molding testing is based on principles of physics and chemistry, and the same tests have been used since the practice began. This lends an extra degree of certainty to the results – because the tests are rooted in scientific principles, they cannot lie and are highly repeatable.

When developing a new product and starting to complete test runs, a series of four to eight experiments is conducted by internal resources. The specific number of experiments varies according to the level of sophistication or complexity of the finished component and the tools that are used to mold it. These experiments include measuring melt viscosity, gate seal, pressure, cavity imbalance and machine repeatability.

When materials and processes are tested, the results are recorded in specific spreadsheets and are charted over time. This allows molders to ensure that the output follows the guidelines associated with each test. Process engineers should test new components, while a team of engineers and product technicians should review existing projects. Special attention should be paid to higher-run projects, critical components or those with special criteria to ensure that output is consistent.

Quality Control

A key consideration in scientific molding is “looking at molding from the plastic’s point of view.” This means that a scientific molder considers both sides of production – the inputs and the outputs. As mentioned earlier, your molding partner should not simply rely on machine parameters when discerning whether specifications are met. For example, the barrel temperatures displayed by a machine are not as accurate as a measurement of the physical melt temperature. Rather than making assumptions about the end result based on historical data and machine settings, a scientific molder should take time to thoroughly test the finished component to be certain that the specifications are met.

Scientific molders take great care to thoroughly document test results, product design specifications and other key data. A universal process sheet should be created for each project, to capture critical information and create a link between the process inputs and the project output. This sheet helps provide essential data required in an audit and creates a historical trail that can help with troubleshooting. When choosing a scientific molding partner, be sure to review their documentation practices to ensure that their process includes all required information.

Reporting and Analysis

Reporting is a key element of scientific molding, and reinforces the other three elements we’ve discussed: training, testing and quality control. Because scientific molding is based on a set of experiments, solid data collection practices and reporting are essential to enforce and reinforce the principles. As projects are tested and processes are defined, results are captured along the way and analyzed to determine whether they align with predetermined guidelines.

A good scientific molder will make the collected data readily accessible, not just for audit purposes but to allow you to gain greater insight into your project’s methodology. This is especially important in cases where you are providing the material to your molding partner and are seeking to reduce waste. By reviewing past run data and material test results, you can easily pinpoint any potential adjustments and spot inefficiencies.

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The Key to Consistency

At MRPC, scientific molding has helped us improve our processes and the results we provide to our customers. For example, we were experiencing issues with initial runs of a large polycarbonate container that was developed by a client. By applying the principles of scientific molding to the project, we were able to define specific parameters for the project that reduced the level of scrap material and rejects from each run. While some defects are inevitable during startup, we were able to minimize these issues which saved the client material costs and improved efficiency.

Scientific molding is not a fad – over the years, these principles have become deeply ingrained in the molding industry. When assessing molding partners, be sure to create a set of requirements for your vendors that align with the principles of scientific molding. This will ensure that you get the best results – every time.

About MRPC

MRPC is a single-source provider of innovative medical device components and assemblies, specializing in clean room molding with a focus on silicone molding, two-material molding and micromolding. As an FDA-registered manufacturer, MRPC is committed to providing our customers with the highest level of expertise through extensive staff training, industry certifications and a long history of success.

