Introduction

One of the most important responsibilities undertaken during the development of a new product is designing a robust manufacturing process that consistently meets the needs of the customer. Significant problems can occur during full-scale production when manufacturing processes are poorly conceived. If one is lucky, these problems are caught during product qualifications or during pilot manufacturing; however, this is still not an ideal state. Therefore, it is incumbent upon research and development organizations to employ effective procedures for ensuring sound manufacturing process development.

Project management tools, such as New Product Development Processes (NPDs) and quality tools, such as Lean Six Sigma, Design for Six Sigma (DFSS), and Design for Manufacturability (DFM) provide much value when undertaking the development of new products. However, in general these tools do not explicitly instruct how and when to apply scientific and engineering knowledge over the course of process development efforts. In the absence of good science and engineering, quality will always be deficient, regardless of the merits of the tools employed.

The objective of this article is to introduce a novel phase-by-phase approach for ensuring rigorous use of the scientific method and engineering knowledge when developing a manufacturing process for a new product. When this methodology is followed carefully, one can have confidence that scientific understanding has been well-considered in product designs and that engineering choices have been based on a sound methodology. Ultimately, this approach can lead to new manufacturing processes that are more robust and optimized and meet the needs of the customer.

New Product Development Processes

Much attention today is focused upon developing a good New Product Development Process (NPD or PDP). NPD systems control the new product design and development activities of the organization and are designed to meet the requirements of ISO 9001 section 7.3. Typically, NPD projects consist of several stages, each gated by a management

<table>
<thead>
<tr>
<th>Phase</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1</td>
<td>Project Initiation</td>
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<tr>
<td>2</td>
<td>Concept Investigation/Business Case</td>
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<tr>
<td>3</td>
<td>Development</td>
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<td>4</td>
<td>Validation/Implementation</td>
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<tr>
<td>5</td>
<td>Manufacturing Scale-Up/Commercialization</td>
</tr>
</tbody>
</table>

Table A. New product development process.
Each gate has required deliverables and represents an overall project decision point. While every organization has its own new product development process tailored to its specific needs, they typically consist of the general activities in Table A.

This article focuses on manufacturing process development, which is only one, but a critical component of new product development. Manufacturing process development is typically accomplished during primarily the “development” stage of NPD projects (though some efforts might be conducted beforehand).

In the earlier stages of an NPD project, the new product, its business case, and its project plan are conceptualized, investigated, and detailed. But once the project team has demonstrated feasibility and has outlined the needs and scope of the project, management must make the critical decision whether to allow the project to move into a development stage. During a development stage, significant resources are utilized to turn the product design into a reduction-to-practice in a manufacturing environment. Engineering practices are an invaluable tool for new manufacturing process development.

The benefits of rigorous scientific and engineering practices during development stages quickly materialize during the subsequent stages of the NPD project. Often, these later stages include a final validation of the product performance claims and the manufacturing process. In addition, there is typically a pilot production stage involving scale-up and the evaluation of the performance and capability of the manufacturing process over time. If the manufacturing process is developed poorly, these stages will prove problematic. Ultimately, sound linkage of the manufacturing process to the appropriate scientific and engineering principles is absolutely critical. The engineering practices approach presented here provides a methodology for achieving this linkage.

### The Scientific Method

The phases of the scientific method are familiar from general education and early scientific training. The scientific method applies not only to simple experiments, but also to the most complex experimental work involving intricate models. Engineering practices, as will be described later, have six phases that reflect the scientific method. The phases of the scientific method are listed in Table D and are compared to engineering practices.

#### Engineering Models

Developing manufacturing processes requires use of engineering models. In the simplest terms, we can define a model as a relationship between inputs and outputs. A good model is necessary for process optimization and scale-up. Models can be simple or complex, and they are incorporated into the Engineering Practices method proposed in this article.

The DMAIC philosophy is particularly valuable when making an improvement to an existing process with an historical baseline; however, from a research and development perspective, more is required when introducing an entirely new manufacturing process. Accordingly, the DMADV approach in DFSS is more geared toward new processes. But unlike Lean Six Sigma and Design for Six Sigma, the engineering practices method stresses the importance of gathering scientific and engineering facts, making engineering hypotheses, and building an engineering model to fundamentally understand the manufacturing process.
also must include a visualization and/or understanding of what the inputs and outputs mean physically. Models can be empirical or theoretical. They can be as simple as a linear regression or as complex as a supercomputer computation.

The concept of “inputs” and “outputs” as they apply to a manufacturing process are mostly quite familiar, though sometimes quite subtle. Inputs typically include the machine parameters and settings and the raw materials. Yet often there are other factors, sometimes highly unanticipated, and these could require special root-cause analysis problem-solving methods.8 The body of input factors could involve the factors listed in Table E.

The outputs are the measured characteristics that relate to the customer, product design, process, and performance needs. Just like inputs, we often mistakenly assume that useful and critical outputs are easily measured; frequently they are not. Ultimately, our model is only as good as the inputs and outputs that we can identify and measure.

Engineering practices uses the basic scientific method, applying the concept of a manufacturing process model. Examining Table C again, we can see that each stage of the scientific method has meaning in the context of an input-output manufacturing process model. “Defining the objectives” entails knowing what the outputs are, how to measure them, and what the values must be as required by the customer. “Forming a hypothesis” means making an educated prediction about the relationship between the process inputs and the outputs. “Testing hypotheses experimentally” requires proving the proposed relationships between inputs and outputs. “Refining and repeating” means conducting further experimentation, e.g., using Design of Experiments (DOE) to establish a more intricate relationship between the inputs and outputs.9-10 “Confirming” includes running a final experiment in order to demonstrate that the model is correct. As will be explained below, engineering practices employs the scientific method in the context of a process model.

“Mirroring the scientific method and requiring use of quality and statistical tools, this methodology ensures a good science and engineering approach to the problems at hand.

Table E. Six types of input factors, often referred to as the six Ms that can influence ultimate output.

<table>
<thead>
<tr>
<th>Factor</th>
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<tbody>
<tr>
<td>1 Machine operators (“man”)</td>
</tr>
<tr>
<td>2 Machines/equipment</td>
</tr>
<tr>
<td>3 Materials</td>
</tr>
<tr>
<td>4 Methods/procedures</td>
</tr>
<tr>
<td>5 Measurements</td>
</tr>
<tr>
<td>6 Manufacturing environment (“Mother Nature”)</td>
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Engineering Practices Approach

A methodology called the engineering practices approach is introduced here for developing manufacturing processes for new products. This is a fluid phase-by-phase process with issues to be resolved and activities to be completed at each phase. Mirroring the scientific method and requiring

![Figure 1. Phases of the engineering practices approach.](image)
use of quality and statistical tools, this methodology ensures a good science and engineering approach to the problems at hand.

The process can be depicted as shown in Figure 1. There are six fluid phases, starting with “Objective Statement,” that result in a final process. Each phase represents a stage of the scientific method. The results of the work, usually documented and detailed in a Process Development Technical Report, become an important part of the new product Design and Development Reviews (required for satisfying ISO 9001 part 7.3.4). The next section will review the six phases of engineering practices and the actions that occur in each phase.

This process is not intended to represent a linear series of managed decision gates, but a flow of “semi-linear” activities. The project team proceeds from one phase to the next when the requirements of each phase are completed. There are no stage gate reviews; the decision to move forward can be made more informally, for example, by consensus at a cross-functional team meeting.

Note in Figure 1 that arrows are drawn from each phase back to any previous phase. During the development of a process, any number of new “learning events” could occur that could not have been anticipated. When it is discovered that scientific understanding must be refined, a project team following good engineering practices will step back to an earlier phase and conduct the activities deemed appropriate. Again, the decision point to move backward would be informal, as made in a cross-functional team meeting.

For example, in the Process Model Development Phase, it could be discovered that there is an additional unknown factor unduly influencing the results. In this instance, the project team might consider revisiting engineering review activities in order to discuss the observations and develop a new model for what may be occurring. After experiments reveal the cause of the problem, the project team may decide to quickly return to the Process Model Development Phase.

Going “backward” may seem like it will introduce significant project delay. This, of course, can be true to a degree; however, forcing the project quickly down a rigid linear timeline rather than permitting a fluid pathway will ultimately incur greater cost. Often, this will take the form of development projects failing, manufacturing quality problems, murky validations, and ultimately longer project delays. Engineering practices, on the other hand, provides an opportunity to solidify understanding of the science and engineering principles and idiosyncrasies of a new product’s manufacturing process before validation ever begins.

**Stage 1: Objectives Statement**

The first phase of engineering practices, the objectives statement, is a list of requirements that are ultimately translated into a set of specific output tests.

Consider the following example depicted in Figure 2. This is a thermal bonding process in which two thermoplastic films of similar composition are squeezed together by heated platens. One output for this process could be the peel strength of the bond which is formed. The project team may want to refer to an appropriate ASTM or international standard for conducting the test. Ideally, there would be a specific target value ensuring the required product performance. Another output could be a functional test of the fabricated final product, the customer-required test result being known.

For most new product development projects, particularly in order to meet the requirements of ISO 9001 section 7.3.3, the customer, design, performance, and process needs are clearly laid out in a negotiated design specification document for the new product. Thus, it is important that a design specification, as much as possible, be completed and finalized when process development begins.

Clearly, it is neither practical nor necessary to perform every single product performance test measurement described in the design specification as the output of each and every designed experiment (DOE). Thus, a key step in this phase is determining which requirements are the most applicable to the process or processes under consideration. The process output tests, or responses, should ultimately reflect the issues of highest risk and the attributes most greatly influenced by the process.

At this point, it is highly appropriate to critically evaluate...
The design specifications themselves to determine whether the requirements are reasonable and if there is adequate evidence to support the needs. While much previous work, debate, and negotiation likely went into developing the design specification, it would be quite tragic to optimize a manufacturing process to meet requirements that are incorrect, unrealistic, or for any other reason require significant revision later in the project. As an analogy, when piloting a plane from New York to Las Vegas, we would not want to discover somewhere over Colorado that the destination from the beginning should have been Orlando.

Output tests also should, as best as possible, meet the general requirements of a good response. Ideally, they should be quantitative and readily measured. The needs of an output test also will be taken up in Stage 4: Engineering Model Evaluation.

Stage 2: Engineering Review
The purpose of the engineering review phase is to explore all relevant data and information pertaining to the product, manufacturing process, and the objectives statement. During a good engineering review, the project team will survey all important and relevant sources until able to form a working hypotheses or hypothetical model of how the manufacturing system works.

An important part of the engineering review is to assess whether the task at hand is part of a large previous body of knowledge or a relatively new area. If the new product and fabrication processes have similarities to others that have come before it, the sources of information should be, in most cases, relatively voluminous and easy to find. On the other hand, if the new product is unlike any that has been manufactured before, the search for information will be more difficult.

Sources of information can be internal and/or external to the organization. Common reliable sources of information are shown in Table F.

<table>
<thead>
<tr>
<th>Internal</th>
<th>External</th>
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<tbody>
<tr>
<td>Experts (internal)</td>
<td>Experts (external)</td>
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<tr>
<td>Process literature from similar products</td>
<td>Vendor datasheets/literature</td>
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<tr>
<td>Internal technical literature</td>
<td>Patents</td>
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<td>Internal networking websites</td>
<td>Books</td>
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<td></td>
<td>Journal articles</td>
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<td>ASTM and international standards</td>
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Table F. Common sources of information.

The experience of internal experts is perhaps the most indispensable form of information. Project teams should broadly consider all available expertise in the organization where applicable. Knowledge can be solicited and conveyed directly in conversation and correspondence. Alternatively, experts can be invited to participate in project meetings, such as data presentations, design reviews, brainstorming sessions, and Failure Mode and Effects Analyses (FMEAs).

Internal literature is also a critical source of information. Today, more and more attention is being paid to methods of storing and retrieving organizational knowledge. Often, key process information is found in quality documentation, including validation reports, Standard Operating Procedures (SOPs), and lot record forms. Often, written technical reports and memos are housed within searchable corporate database systems. More recently, companies are turning to web-based systems and “social networking” tools to deposit information and foster collaboration.

The World Wide Web is clearly one of the mostly used tools for locating and/or downloading external information (typical sources listed in Table F). However, when using the internet, one should remember that information is only as reliable as its source. Websites are ever-changing and can reflect misconceptions and biases on the part of contributors.

Stage 3: Preliminary Engineering Model
The preliminary engineering model is a qualitative or semi-quantitative hypothesis of how the system operates. Thus, at this phase, we would state the model’s inputs, outputs, and expected main effects and interactions.

A key to this is properly identifying all of the critical inputs and outputs. Inputs would typically include key process parameters, but also include other factors, such as raw materials. Outputs could include functional tests on end product, but also could include in-process measurements or examinations. When there are qualitative visual outputs, it is always a good idea to develop a semi-quantitative ranking scale. In this preliminary engineering model phase, tools such as a SIPOC diagram, shown in Figure 3, may be helpful.

Explaining the expected relationships between inputs and outputs is not always straightforward. Clearly, not all relationships are expected to be direct and linear. Typically, there will be relationships and/or interactions between input parameters. And often, there will be curvature and optimum conditions; therefore, these relationships should be understood and detailed before moving forward.

For the plastic thermal bonding example described previously (see Figure 2), inputs could include parameters such as temperature, force, and time. As part of the preliminary engineering model, the team may hypothesize, for example, that if the temperature is not sufficiently above the melting point of the plastic, the bond will not adequately form. Fur-
thermore, the team may add that if the temperature is too high, the seal may crack or burn. Regardless, it is important to first foment an engineering understanding of the system, though at this point, the understanding may be hypothesized from experience, but not yet proven for this specific manufacturing process.

Also, there will be side effects and limitations. In the simplest case of a limitation, it may be impossible to modify an input parameter beyond a certain point. Alternatively, it may be impossible to produce product when parameters are combined in a certain way. Furthermore, modifying a parameter beyond a certain point may introduce an entirely new set of undesired risks or issues. Thus, all of these considerations must be part of the hypothetical model as they greatly affect the selection of final parameters.

Clearly, it is impractical to investigate every possible parameter. Thus, it is critical to determine what should be included and what should be omitted. This, of course, is helped by a sturdy technical understanding of the process itself. While investigating fewer parameters brings risk, investigating too many parameters dilutes the effort from what is most critical and important.

Often, there may be entire process steps that can be justifiably neglected. This is okay as long as the assumptions can be justified. For example, there may be a long successful history of running that particular process step with the new product in question, introducing nothing new that should reasonably alter it. The ultimate objective is to avoid, on one hand, taking foolish risks, and on the other hand, wasting valuable engineering time on unnecessary activities.

At this point, it would be advisable to review the new product’s preliminary Failure Mode and Effects Analysis (FMEA) or initiate one if one does not exist. The preliminary engineering model should speak to the process risks anticipated to be the highest.

**Stage 4: Engineering Model Evaluation**

Engineering model evaluation is the substantiation of the hypothetical model. That is, it is the generation of data that proves (or disproves) the preliminary engineering model.

This phase actually has multiple steps. The first step is demonstrating that the system is adequate for collecting data. The next step is planning the experiments. Finally, the experiments themselves, typically screening and ranging studies are run.

There are several objectives of showing the system to be ready for experimentation. Essentially, it important to assure that:

- There is sufficient control of the critical input parameters.
- The output measurements have the needed precision.
- The appropriate sample sizes have been calculated.
- The inputs can be varied enough to observe the expected range of performance.

This article is not intended to delve into the tools for accomplishing the above; however, equipment calibration, gage R&R studies, power and sample size calculations are central to this phase. It is also important to ensure that equipment meets the requirements of ISO 9001 section 7.6 for the Control of Monitoring and Measuring Equipment.

Once the system is acceptable for experimentation, the next objective is to prove (or disprove) the preliminary engineering model. This is ordinarily accomplished using screening and ranging studies. Screening studies test all potentially important variables in order to identify those with statistically significant effects. Ranging studies identify the feasible operating range of the process, seeking the edge of failure. In some situations, the edge of failure is never met, and in those cases, the objective is to demonstrate that the feasible operating range is much wider than the anticipated process range. Screening and ranging studies can be considered complete when and only when they successfully prove a complete preliminary engineering model.

At this point, it may be possible to utilize data from screening and ranging experiments to construct a quantitative predictive model. This model can either be theoretical or empirical, but should form the basis for the continued process development work.

At the end of this phase, it should be possible to propose a feasible range of operation of the parameters. This will not necessarily be the optimized range or even a capable range. However, it should address all of the key parameters and provide an approximate window of successful operation from which we can begin to optimize the process.

**Stage 5: Process Model Development**

During the next phase, process model development, a more
in-depth series of DOEs or other structured experimental studies are conducted. The results are used to generate or further refine the process model. The desired outcome of this stage is an optimized process window and a data-driven predictive model that supports it.

Ideally, a series of overlapping DOEs will be conducted until the process is optimized. There exist various methodologies for designing sequential experiments for the purposes of finding optimum process conditions.\textsuperscript{14,15} The series of experiments should not only elucidate the optimum window in which to operate, but also provide the data needed to generate a strong input-output model for the process. In the thermal bonding process example (see Figure 2), a linear regression model might be developed for predicting bond strength as a function of temperature, force, and time (if those are the critical parameters determined).

In this phase, having had a good objectives statement is critical. This is because from the objectives statement comes the definition of the optimized state. Often there will be tradeoffs, and in those cases, reasonable methods must be employed to determine how to weigh them. But without an unambiguous and reasonably fixed desired endpoint, optimization to that endpoint is at best problematic.

Incorporating worst-case input materials into process experiments is highly recommended in this phase. Worst-case inputs could be actual raw materials or semi-finished products from other manufacturing steps. It may be useful to consult the SIPOC diagram. Especially because input materials can be more difficult to control, it is important to generate confidence that the process under development can handle the range of inputs that could arise during production.

Also, the process development team should be considering the eventual transfers of ownership that often occur after the product is approved for manufacturing. Typically, a research and development team may be mainly responsible for the process development stages and manufacturing process engineers subsequently responsible during production. Clearly, these hand-offs only work effectively when there is solid communication, interaction, and teamwork between all functions during development process.

In that regard, it is highly recommended that manufacturing process engineers and equipment operators be highly engaged with the development project at or before this particular phase. It is also important to clearly document process development work (i.e., in reports, process records, laboratory notebooks, etc.) so that all stakeholders have available to them the information they need to know.

**Stage 6: Process Model Confirmation**
The final phase of the engineering practices approach is process model confirmation. This phase consists principally of a confirmation run. The objective is to demonstrate that manufactured product will meet requirements at worst-case conditions.

Naturally, it is important to consult the process model when defining the optimized process window to be confirmed. From the process model, it should be possible to propose a specific region of operation for the final process. The confirmation run should be an exercise of running the manufacturing process at its final limits that, according to the process model, would produce the worst-case outputs.

Truly understanding what all of the critical inputs are is critical to designing a good confirmation run. As suggested previously, critical inputs will often include a set of machine parameters, but also can involve worst-case raw materials or worst-case inputs from other related processes. All worst-case variables would be included in the ideal confirmation run.

Clearly, a confirmation run should not be a complex DOE requiring many different combinations of inputs. Such experimentation is reserved for the previous two stages. The purpose of the confirmation is not to gain new insights, but simply to confirm that product manufactured at the worst-case limits meets requirements and that the results are consistent with the model.

In that respect, it is important to deal with inputs efficiently and logically. Often, inputs can be grouped together based upon their physical relationships to one another or upon how they impact the key outputs. Some input parameters may be important enough to vary, and some may be held constant. Often, two to four conditions are amply sufficient for a confirmation run. The key is to justify the experimental design with logic and physical reasoning.

**Conclusion**
This article has described a general approach to process development called engineering practices. The overall purpose of this methodology is to define the phases of effort that lead to a well-designed process. When followed, the engineering practices approach will ensure the use of good science, process modeling, and suitable quality and statistical tools. Ultimately, a research and development program dedicated to good engineering practices will result in fewer problems during product validation, scale-up, and full manufacturing.

The results of the process development work should be documented and assessed in a final report and/or design review. Ideally, these should be organized to reflect the above six phases as outlined below:

- Objectives Statement: state the process requirements. Refer to new product specification where applicable.
- Engineering Review: summarize the relevant technical information used to design the process. Provide references.
- Hypothesized Engineering Model: describe the engineer-
The key is to justify the experimental design with logic and physical reasoning.

One might ask whether it is necessary to rigorously work through each phase of engineering practices for every new product development project. The answer, of course, is that every project is different, and each may require more or less emphasis at certain stages. This all depends on how much previous process knowledge exists and how much risk can be tolerated. These can often be assessed during the engineering review stage.

In thinking about the question above, it is useful to imagine two extremes. The first is a new “line extension” product that is very similar in almost every way to those the manufacturing plant has produced for decades with, let us suppose, stunning success. Furthermore, let us assume that the need for the new product is business-critical and that failure to launch the product quickly will have devastating consequences. Clearly, in this instance, a protracted development process is non-advantageous. Here, it might even be possible to recommend final process parameters during an engineering review and jump quickly to a confirmation run.

The second extreme is a new product unlike any other on the market. Furthermore, the manufacturing process involves new and unique machines and equipment. In this instance, regardless of the urgency of the business need, success is virtually impossible without a rigorous development process. Here, shortcuts based on risky assumption will often result in even longer delays. On the other hand, it is proposed that the engineering practices approach described here provides a strong framework for meeting success.

References
uct capability when products are introduced and trained development engineers to accomplish this objective. He completed one of the earliest successful ISO-9000 registrations in the US, 1991. He is also published in areas of QbD, statistical methods for setting specifications, and probability aspects of size based filtration. He can be contacted by telephone: +1-781-533-2928 or by email: Mark.Blanchard@merckgroup.com.

EMD Millipore, 80 Ashbury Rd., Bedford, Massachusetts 01730, USA.

**Salvatore Giglia** received his BS in chemical engineering from Tufts University and MS in chemical engineering from the University of Massachusetts. He is the Principal Applications Engineer at EMD Millipore and has 30 years of experience in the area of membrane based separations. Giglia is listed as an inventor in more than 25 patents related to membrane separation devices and processes, and has authored a number of publications covering various aspects of membrane filtration technology, including integrity testing and scalability. He can be reached by telephone: +1-781-533-2564 or by email: Sal.Giglia@merckgroup.com.

EMD Millipore, 80 Ashbury Rd., Bedford, Massachusetts 01730, USA.

**Greg Straeffer** holds a BS in chemical engineering from Purdue University and MS in textile chemistry from Clemson University. He is the Senior Development Engineer at EMD Millipore working on biosafety filter products. Straeffer has been in the filtration industry for 29 years, 15 of those at Millipore/EMD Millipore. He has worked in the design and development of new filters, but also has had stints in technical market research, applications test development, technical service, and operations. He has been awarded three US patents and has helped launch successful filter products for electrocoat paint systems in automotive assembly plants, ultrapure water systems and CMP systems for semiconductor manufacturing, and clarification and virus-clearance processes in the biotech industry. He can be reached by telephone: +1-781-533-2151 or by email: Greg.Straeffer@merckgroup.com.

EMD Millipore, 80 Ashbury Rd., Bedford, Massachusetts 01730, USA.

**Amy Cazeault** holds a Bachelor’s degree in mechanical engineering from the University of Michigan and a Master’s degree in mechanical engineering from Northeastern University. She has more than 10 years of experience at EMD Millipore working in manufacturing, new product development, and product transfer from R&D to manufacturing. She is currently an R&D Manager for EMD Millipore’s Validation and Applications Center and oversees lab operations. The center is responsible for validation testing of new products prior to market launch. She can be reached by telephone: +1-781-533-3384 or by email: Amy.Cazeault@merckgroup.com.

EMD Millipore, 75 Wiggins Ave., Bedford, Massachusetts 01730, USA.

**Shannon Cleveland** received a BS in 1999 from Northeastern University’s School of Chemical Engineering in Boston, Massachusetts. She is a Membrane Development Engineer in the R&D Downstream Processing group of EMD Millipore.

Cleveland joined EMD Millipore in 2006 after eight years at Polaroid Corporation where she supported the development of photography media. For the past five years, she has developed membranes for sterile filtration, virus removal, and pre-filtration. She can be reached by telephone: +1-781-533-2728 or by email: Shannon.Cleveland@merckgroup.com.

EMD Millipore, 80 Ashbury Rd., Bedford, Massachusetts 01730, USA.

**Matthew Desmarais** is a R&D Manager for Biosafety Device Process Development. He has course work in Mechanical Engineering from the University of Massachusetts, Lowell. Desmarais manages new product development teams via the New Product Development Process from bench-top through validation and release to manufacturing. His recent successes include EMD Millipore’s Viresolve® Pro and Viresolve® Pro + Solutions and the EMD Millipore Express® product lines. He can be reached by telephone: +1-781-533-2352 or by email: Matt.Desmarais@merckgroup.com.

EMD Millipore, 80 Ashbury Rd., Bedford, Massachusetts 01730, USA.

**Rebecca Bartkus** earned a BSME from UMASS Lowell and holds ASQ CQE and ASQ SSGB certificates. She is a Pilot Process Engineer at EMD Millipore, working with R&D to assure the development and validation of new products and processes are robust prior to the release to manufacturing. She has contributed to the introduction of new production platforms and numerous product lines. She can be reached by telephone: +1-603-532-2341 or by email: Becky.Bartkus@merckgroup.com.

EMD Millipore, 11 Prescott Rd., Jaffrey, New Hampshire 03452, USA.