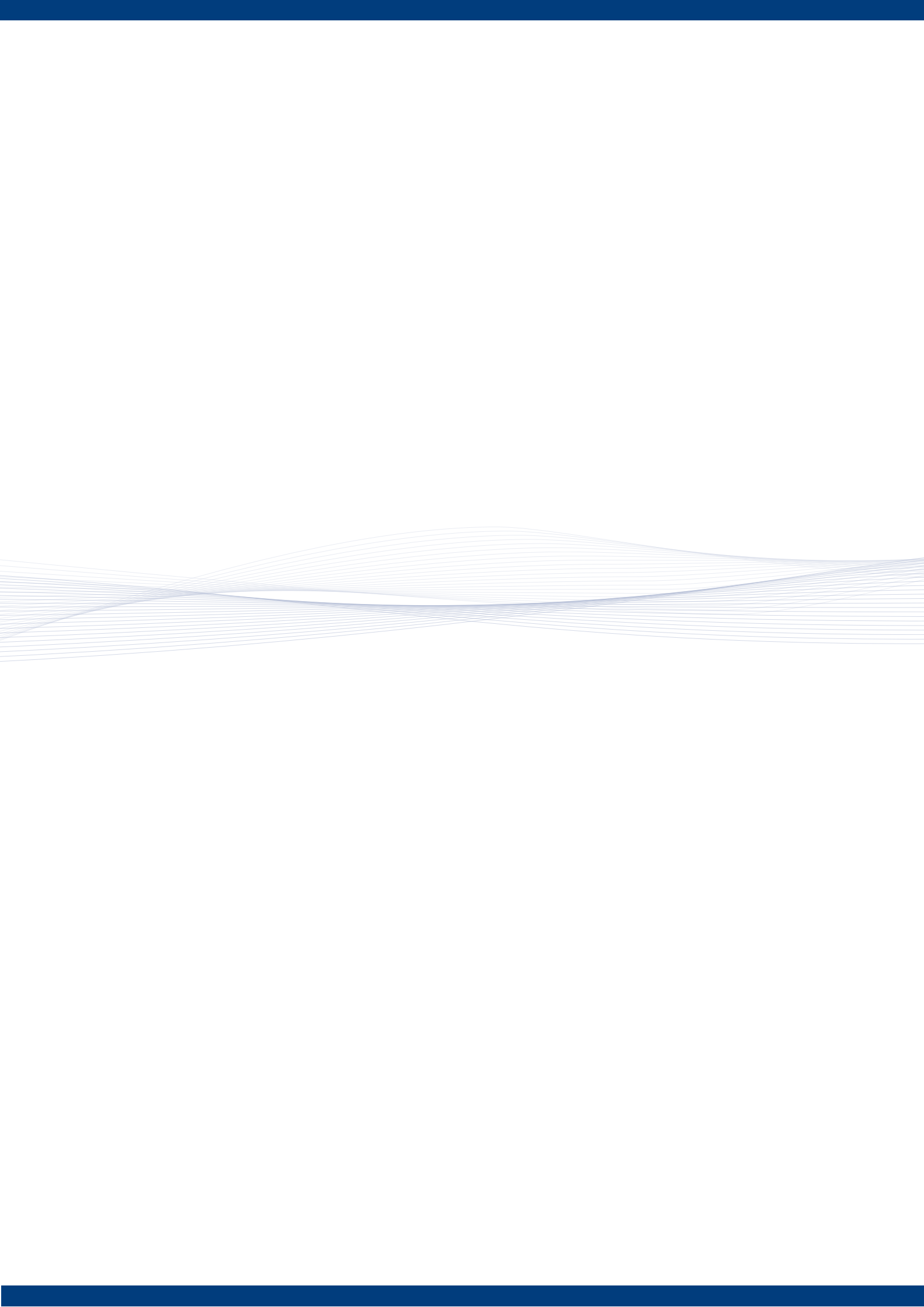


# **“Partnership Assured” – transforming external manufacturing from risk to asset**



# “Partnership Assured” – transforming external manufacturing from risk to asset

In specific high compliance industries such as the pharmaceutical sector, the risk attached to using external manufacturers (EMs) was highlighted some time ago and is being successfully engaged with. Now, with pressure in all other sectors to pursue cost-effective production through alliances and partnerships, risk is present everywhere, from spare parts to soft toys. The challenge is to transform EMs – especially in the emerging economies – from a potential liability to an asset as a source of assured competitive advantage.

## Overview

**The key question for us is this: how can you be fully compliant, work professionally and with a high standard and for reasonable cost?** Senior Director, Pharmaceutical Industry

## The situation today

Damaging headlines - from contaminated therapeutics in the pharmaceutical industry to lead paint on children's toys – underscore the potential risks of working with EMs. Operationally, these risks range from sub-standard product quality, through environmental damage to undesirable associations with poor labour practices.

There have been cases where unsuspecting consumers and patients have become ill or even died, as a result of poor quality products. There are profound implications for consumers, for brand loyalty and trust, and therefore ultimately for the fundamental reputation of businesses.

Companies whose external manufacturing strategies were designed to grow shareholder value may find themselves criticised in the tabloids, rather than praised in the financial press. And even if there is no high profile risk story, many EMs still have progress to make in order to yield the best return on investment<sup>1</sup>.

<sup>1</sup> In recent research by Reed Business Insight, commissioned by Celerant Consulting, a survey among more than 500 professionals in the chemicals industry (drawn from the ICIS database) revealed that average outsourcing ROI aimed for is 19%. The average achieved is 14%.

## How can you make positive changes?

In this paper, we look at some practical, actionable ways you can select, manage and develop EMs. The journey is a transformation: from risk to reward and from potential liability to partner. It begins with clarity in six key risk assessment areas:

1. Product quality – understanding the processes needed to assure quality
2. Supply chain – assuring the ability to deliver, inside lead times and with business continuity
3. Specialised, industry-specific suitability – such as tough (GMP) pharmaceutical compliance
4. EHS – environment, health and safety issues
5. Organisational and financial health of EMs
6. Ethics and business conduct of EMs

## What are the benefits?

Effective selection and consistent, planned development of your EMs delivers the following important benefits:

- Reduced timescales for finding the right calibre of EM
- A coherent portfolio of high quality EMs
- Reduced demands on your internal management time
- Clear focus on measurable EM development (rather than fire fighting)
- Efficient management of increased volumes of diverse products
- Substantial avoided capex
- Major cost productivity benefits in the outsourcing pipeline
- Significant risk reduction

## In more detail The big drivers of external manufacturing

In every sector, companies face erosion of gross profits, pressure on top line revenues, higher R&D spending, and an increased focus on cost efficiencies to drive the bottom line. It is harder to develop the next blockbuster. It demands more research investment. There is more pressure to show the direct benefits of innovations – from likely demand for next generation consumer products, to the clinical effects of new medicines. For every company that wants to remain competitive, and generate enough cash for innovation, trimming the cost base has become imperative<sup>2</sup>.

As a response to the need to protect profits and growth, licensing and acquisition have taken off<sup>3</sup>. Alliances, for example in development and manufacturing of promising late stage clinical products, are increasing. And technology partnerships are forming to make the most of alignments between specialised external manufacturing capability and existing marketing and distribution networks.

## Is manufacturing outside the organisation really the answer to cost reduction?

Outsourcing, typically to EMs in the emerging economies, can achieve positive changes in value creation. Yet many outsourcing strategies have delivered much less in practice than their theoretical potential.

### Risks to maximised value through outsourcing

Managing the cost base down through increased outsourcing poses serious business continuity risks<sup>4</sup>. These occur in fundamental areas such as time-to-market, product quality, environmental impact and employee health and safety. They can jeopardise reputation and top line growth. Ironically, they can actually cost more than the original arrangements. So what are the causes of the risks? And what can you do to reduce and then eliminate them?

### Internal challenges ... leading to external issues

In their search for secure, competitive, reliable and compliant supply from EMs, diverse industries face converging issues:

- Use of EMs is increasing rapidly, creating substantial extra demands on internal management
- There are too many EMs and they are too fragmented, in terms both of location and ability
- There is no defined EM portfolio strategy – so these are not selected according to clear and consistently applied criteria
- There is inconsistent management of EMs across the company
- There is lack of clarity: in key areas, EMs are reacting to disparate and incomplete operational requirements for Quality, Safety, Compliance and Supply Chain integrity

### External Manufacturers are not always at fault

Very often, the issues listed above are caused by a need for more effective planning and clearer focus internally. They are not inevitably generated by missing capability at the external partner's end of the chain. And they will not be managed effectively, let alone be eliminated, until there is a robust alliance and outsourcing management system in place.

## Alliance and outsourcing management system

Of course, good supplier management is focused on performance<sup>5</sup>. But the scope of what is addressed in the journey to partnership needs to be much broader than productivity and cost alone. Over time, it should ensure development in important areas including EHS, Quality, Supply Chain, Technology, Technical Expertise, and the EM's organisational maturity.

### Turning suppliers into partners – what do you need to do?

- Clear process for making initial strategic decisions on outsourcing
- Strong, clear processes for selection, qualification and development of external partners
- Robust performance management, including financial and operational monitoring
- Clear process for assessment and mitigation across all key risk categories
- Solid process for building sustainable partner performance capability for the medium and long term

### Good building begins with good architecture

Initially, many companies will not have in place all the elements listed above. And their depth and robustness will vary. But there is one constant: the pivotal factor that makes companies successful in managing EMs partnerships is their Alliance/ Outsourcing Performance Management architecture.

The architecture links the company's external production network to its outsourcing strategies. It sets out a clear process for decision making on outsourcing and partner selection. And its partner development component focuses on action planning, execution and follow up.

Applying the architecture, companies can build external manufacturing capabilities faster, manage enhanced performance, and mitigate risks more effectively. This leads to assured time to market, best cost productivity, sustained quality and business continuity. And last but not least, it helps trusted brands stay out of the papers – except when the news is good!

## Turning plans into reality – start with a road map

Historically, many EMs have been chosen “organically” with selection driven by tactical issues. Managers need to start the transformation process by developing a consistent set of selection requirements. It is useful to have a “road map” – a reality-driven plan that captures in detail where you are right now with your external manufacturing capability, and where you want to be within a realistic time frame.

First base questions include the following: do you have the right internal resource to manage outsourcing and licensing and acquisition? Do you have enough people and are they the right people?

This is a good time to clarify the fundamentals: what is your definition of the “right calibre” of EM? Is it consistently applied? How many of your current EMs measure up? And, if they don’t, how quickly could you improve them? (Assuming that’s feasible.)

## Using the map, begin the journey

Even if initial analysis confirms that your current EM resource is not ideal, you have to start with what you’ve got. It is very unlikely that operations can be suspended while you terminate EMs and search for replacements. Instead, use the experience and strengths that your EMs already have, but in more structured and consistent ways.

Clarify roles and responsibilities internally and externally, so that both your management team and your EMs know exactly what is expected. Standardise processes and workflows across the EM portfolio – although not an overnight task, it will quickly pay dividends in terms of consistency and predictability. And put in place a custom built Management System (MCRS<sup>®</sup>) so that you have steadily increasing real time knowledge of how all your EMs are performing.

Within weeks, your internal management teams will have far better visibility into EM performance against shared standards. They will see where they need to focus their efforts in terms of individual areas of weakness. And they will see which EMs are capable of moving forward with greater responsibility.

## Results focus and building capability to deliver results

Results are not an abstract. You can only deliver them by understanding your EMS' current capabilities and weaknesses, targeting support and providing consistent process. But, once you have reliable management information on your EMS as “basic suppliers”, you can start to move them up the food chain towards partnership.

Look at your overall strategy and begin to align your approach to your EM resource with it<sup>6</sup>. EMS that are already producing quality product, consistently and at best cost, have got to first base. Now, they can be engaged to deliver more of your product portfolio. You may decide at this point to get closer to them as partners. This can involve building their capability through development planning, management selection and training and greater commitment through revised contract arrangements.

As your involvement grows with the best and strongest of your EMS, you will start to influence more directly how they function – culturally and strategically, as well as on the production floor.

You may decide to prepare them for more sophisticated manufacturing challenges, including responsibility for higher added value elements of your product portfolio, or even actual innovation through R&D.

The journey may take you as far as a full alliance, with shared targets and rewards, shared profit and even joint equity investment.

A sophisticated relationship with a delivery partner, at the centre of your portfolio strategy, is the end of the journey. It is a very long way from putting basic standards in place to ensure compliance and avoid damaging headlines. But it is both feasible and achievable - in shorter timescales than you might think. It relies however on a fundamental realisation. This has to be made by senior management and then acted on.

## Capacity is NOT the same as capability

Picking suppliers because they can deliver – on paper at least – the quantities needed at the price the market demands does not equal an EM strategy<sup>7</sup>. As an approach, it has led to frequent and high profile examples of non-compliance with the demands of safety, quality and business continuity. It has proven to be a false economy. And it has clearly shown that the capacity of an EM is not the same as their actual capability.

Successful (defined as safe, reliable, and cost-effective) delivery depends on action through implementation. Companies who develop an optimal EM portfolio will implement the following:

- A roadmap for selection and qualification of EMs
- A roadmap for manufacturing and development of External Manufacturing Partners
- A Management System (MCRS<sup>®</sup>) to manage EM performance & organisation
- Clear Project Management, Portfolio Management, and Resource Management for introducing new products to new External Manufacturing Partners
- Clear decision making and execution process for key sourcing decisions and strategy; what to outsource, to whom, and why

Implementing a clear EM Strategy, building real capability, and designing a truly “Fit for Purpose” EM Organisation will lead to the following clear benefits:

- A streamlined decision making process for outsourcing, with clear criteria, mutually understood responsibilities and faster and better EM execution
- A single, coherent way of selecting, qualifying, developing, and effectively managing EMs to become Partners
- A clear governance structure to effectively manage and reduce the risks of supply disruptions and impact on revenues and cost
- A clear pathway to building both individual EM capability and a cohesive total EM organisation

<sup>7</sup> Yet On Time and In Full is cited by 77% of ICIS respondents as the most important selection criterion for outsourcing partners, followed by cost (73%) License to Operate (72%) and Technical Expertise (70%) Ability of the outsource to work as a partner ranks much lower as a selection criterion (42%)

## Conclusion: External Manufacturers – achieving the optimum situation

Clear strategy backed by practical implementation is enabled by good processes, good systems and good people. This leads, among many other positives, to behaviour change through collaboration; as opposed to wasteful internal competition and external confusion.

Transparent decision making, clear goals and a shared language inevitably lead to sustainable results, including but not limited to:

- Top line improvements, with revenue and income increased
- Major reduction in operational expenses
- Lower CAPEX

EMs, if selected and managed well, will do a lot more for your operation than saving money alone.

If you have a carefully chosen portfolio of external partners you can count on:

- A consistent ability by your partners to provide you with the highest possible quality of product, at the best possible price
- A supplement your existing bandwidth that does not drain management time and attention<sup>8</sup> since your partners will require a minimum of direct day-to-day supervision.
- Partners who are capable of growing with your enterprise and supporting its strategic aspirations, by becoming more technically proficient over time.

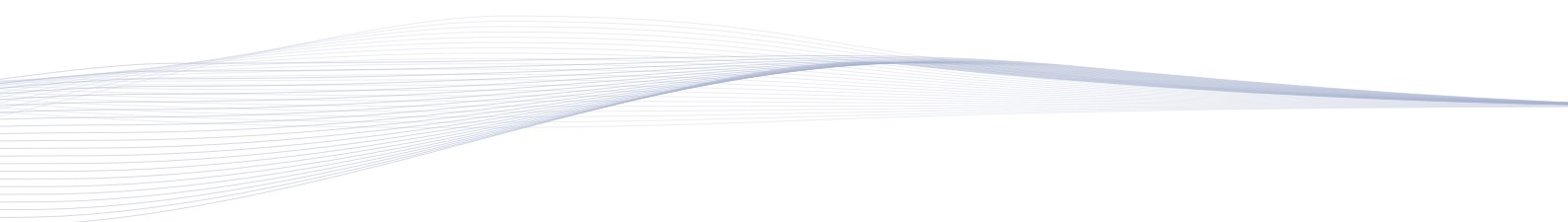
The destination is nothing less than a ‘virtual’ manufacturing site. This consists of a carefully chosen portfolio of external alliance partners, who can be trusted to deliver on time and in full to your standards.

Getting it right with your EMs means there is no separation between the quality you produce in Brussels or Baltimore and their output from Bangalore or Beijing.

The only differences are positive: production efficiency, price and competitive advantage. Instead of ‘suppliers’ you are working with compliant, reliable and cost-effective alliance partners. So not only is your bottom line protected. So is your reputation.

## More points of view on supplier development

The effective development of EM partnerships is central to a cost-effective manufacturing capability. But there are situations where partnership is not appropriate. There will always be a role for the straight supplier relationship. In a companion paper to this piece – “Suppliers – from Involvement to Commitment” – written by Martin Laub we look at the ways in which you can assess, develop and maximise supplier performance to drive your business.





## About the Author

### Erik Tieleman

Erik is a Senior Project Manager with Celerant. During his 18 years in consultancy and industry (paper, packaging, chemical, pharma, medical device, healthcare), he has undertaken a wide range of global and transformational assignments in the Private Sector covering a variety of business functions, from R&D, Marketing & Sales through to Operations and Supply Chain. Erik specialises in creating business results through the delivery of sustainable behavioural change to clients, and the delivery of tools and techniques which include: Operational Excellence (Lean & Six Sigma), Program/Project Management, Supply Chain, External Manufacturing/Outsourcing.

Erik is a seasoned Six Sigma Master Black Belt, has driven multi-million \$ productivity improvements in the Netherlands, Belgium, Germany, France, Italy, UK, USA, Japan and has been applying Process Excellence and business improvement principles for over a decade. Erik has a Business Administration degree from the University of Groningen.



## About the Author

### Martin Laub

Martin Laub is a Senior Project Manager with Celerant, and also leader of Celerant's Integrated Supply Chain Capability for our German business. With over a decade's experience in consulting, Martin's work with clients has spanned a number of industries (predominantly in Manufacturing), addressing a number of key business issues, specialising in the domains of Supply Chain Management, Supply Chain Performance Management, Sourcing & Procurement, Supplier Management, Operational Strategy and Business Management Systems and associated business processes. His work has results in considerable benefit realization for his clients, and several of the projects he worked on won industry awards.

Martin has spoken at numerous conferences, and has published articles focusing on the themes of Integrated Strategic Sourcing and Supply Chain Intelligence.

Martin has an MBA from the University of Rhode Island (USA), and gained his initial degree in Industrial Engineering from the College of Rosenheim, in Germany.

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