IS YOUR OUTSOURCING PROJECT "OUT OF MIND AND OUT OF HAND"

by John Johnson

In the global market, outsourcing is no longer an option, it is an economic necessity. It can be a tremendous asset to integrate another firm's capability and expertise into your network; and conversely, it can add complexity, additional cost and unpredictable risk into the supply chain. So how do you know if it's a good idea or not?

Risk management across a global supply chain has never been a stronger factor in assuring economic success than it is now. Emerging pharma hubs are springing up across the world and this provides us with many more options on where to place our valuable assets. Global communications, the growth of pharma knowledge and the broadening of scientific knowledge in newer locations have all contributed to a wider and more complex set of options.

The process of outsourcing has always been well defined, yet surprisingly not always well managed. The following key steps define the process (yet how many of these are in place and under control in your organization?):

OUTSOURCE PARTNER SELECTION

- Identify potential outsourcing partners
- Questionnaires to help you identify them
- Site visits
- Initial systems-based GMP inspection
  - Due diligence assessments, including business continuity planning
- Quality technical agreement
- Pre-production detailed GMP inspection
- Pre-production technical reviews
- Including decision on person in plant and setting up a technical partnership

INITIAL MANUFACTURING BATCHES

- Proof of concept batches
  - Can be small scale, but less risk at production scale
- Revision of quality technical agreement following technical and quality audits
- Engineering batches
- Process validation batches
  - Perform stability testing of outsourced material, e.g. Active Pharmaceutical Ingredient and final/or Drug Product (DP)
- Manufacturing of a bio batch
  - Includes stability testing of outsourced material and final DP
  - Can include some bioequivalence studies

Once the new contractor is established, a proportionate and insightful oversight program is needed and this will often include considerations for a person in plant, a management review process and technical/GMP on-site reviews.

NSF is noticing a trend where a variety of pharma companies want a third-party perspective on the suitability of an outsourcing option, seeking a thorough and impartial assessment of risk, distinctly outside of the influence of internal politics and financial targets. From such a review, NSF can measure the resource burden of setting up and providing ongoing monitoring of the outsourced location, the inherent risks and how to identify and manage them effectively. We can advise on any operational or GMP remediation programs needed to ensure the manufacturing location can provide a GMP compliant product "on time in full" and "right first time".

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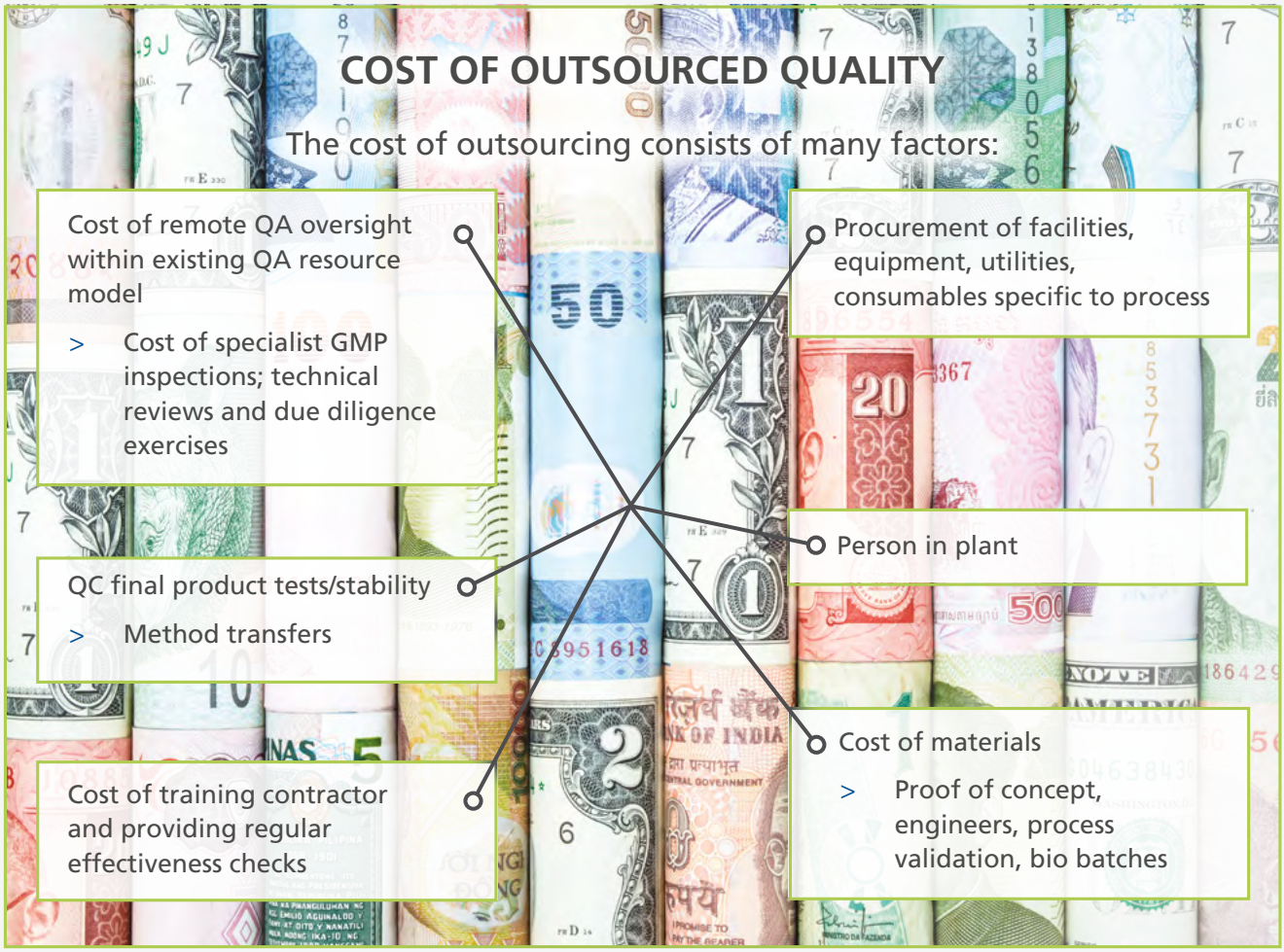
We have supported firms in finding contract laboratories and contract manufacturing organizations associated with sterile products, specialist biomaterials, non-steriles and APIs. We have performed due diligence assessments, business continuity plans and operational and quality reviews, allowing firms the 20:20 vision that is required to make the right decision for the right reasons.

See the information on priorities, costs and key messages when contracting out a manufacturing process.



KEY MESSAGES

> Keep a very close eye on your contractor – risk levels tend to change quickly!

> Key hazards include:

- Initiative overload
- New business
- Staff turnover
- Management changes
- Regulatory expectations change without contractor's full attention
- Contractor not turning out how you thought they would

CONTRACTING OUT – KEY LEARNINGS

The main takeaways from contracting out include:

- Outsource only for the right reasons and only to specialist proven contractors
- Use risk mitigation techniques in making the decision
- Work up a realistic budget for set-up and ongoing mentoring
- Be aware of and take action in the initial period
- Be detailed at management review
- Use specialist highly experienced GMP auditors and person in plant
- Ensure contractors are treated as an extension of your team and an integral part of your pharmaceutical quality system
- Select highly characterized products or low-risk dose forms to be carried out, e.g. formulation and fill/finish

NSF performs these types of assignments with a variety of firms across the world and can differentiate between good and bad decisions, and between solid and risky strategy. Allow us to help you avoid the heartburn of a risky sub-contractor. Contact us at **pharmamail@nsf.org.**

ABOUT THE AUTHOR

John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry.

He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms.

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NSF INTERNATIONAL | PHARMACEUTICAL SERVICES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 I **E** pharmamail@nsf.org

789 N Dixboro Rd, Ann Arbor, MI 48105, USA
T +1 202 822 1850 I **E** USpharma@nsf.org

www.nsf.org I **www.nsfpharma.org** I Follow us on LinkedIn & Twitter