Justifying Investments in Manufacturing Execution Systems

Guidance for life sciences companies considering an investments in MES

Financial Justification

Net Present Value (NPV) analysis puts alternatives on an equivalent basis for comparison and risk analysis.

- Evaluate investments in MES versus other alternatives
- Express a potential project in realistic financial terms
- Evaluate the gains and losses by sources impacted by the MES project and expressed in ROI
- Determine the upside and downside cases to convey understanding of the financial risk

Express these financial impacts as Net Present Value

Net Present Value

The sum of all future cash flows discounted to the present

$$\mathrm{NPV} = \sum_{t=0}^{n} \frac{Rt}{(1+\ i)^t}$$

Future Cash Flow

Any incremental expense or any incremental benefit in real dollars that occurs in the future due to this project

Operational Justification

Based on the risks associated with the process and system capabilities, such as:

- Manual operations
- Compliance
- Sample tracking
- Raw material
- Data collection

If these risks are too great, MES is needed

ISPE GAMP MES Good Practice Guide[1]

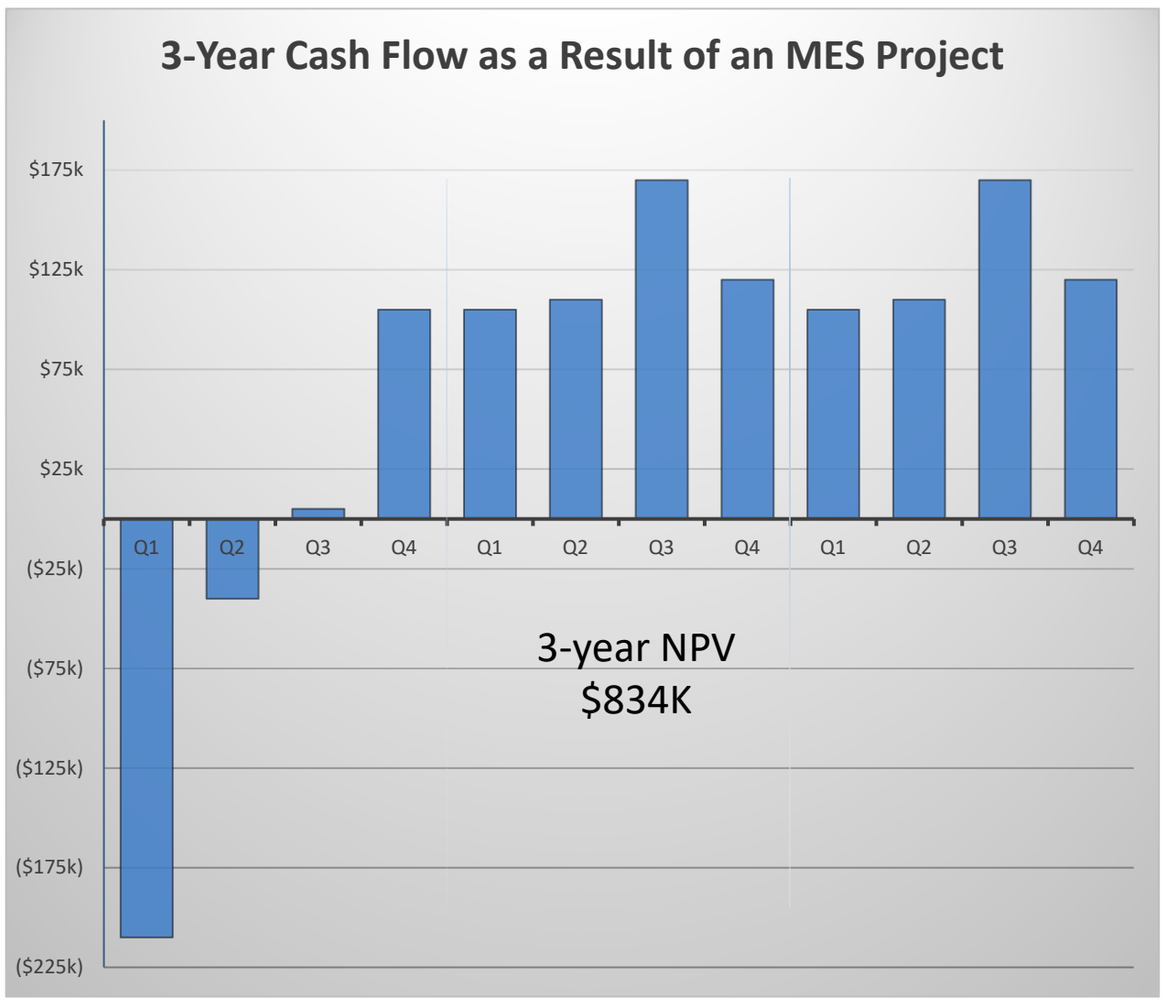
The ISPE GAMP MES Good Practice Guide provides an overview of a strategic assessment to evaluate:

- The current status of the business pertaining to manufacturing systems requirements.
- The desired state of systems requirements to be achieved including breakdown of high-level required functionality in order to advance the business while managing costs.
- Analysis providing assignment of desired functionality already in existing systems, and any needs for new systems to be added to the domain (Automation, MES Application, ERP, QC, Data Historian, etc.)

Output from the strategic assessment will provide a roadmap which should include justification for MES application functionality.

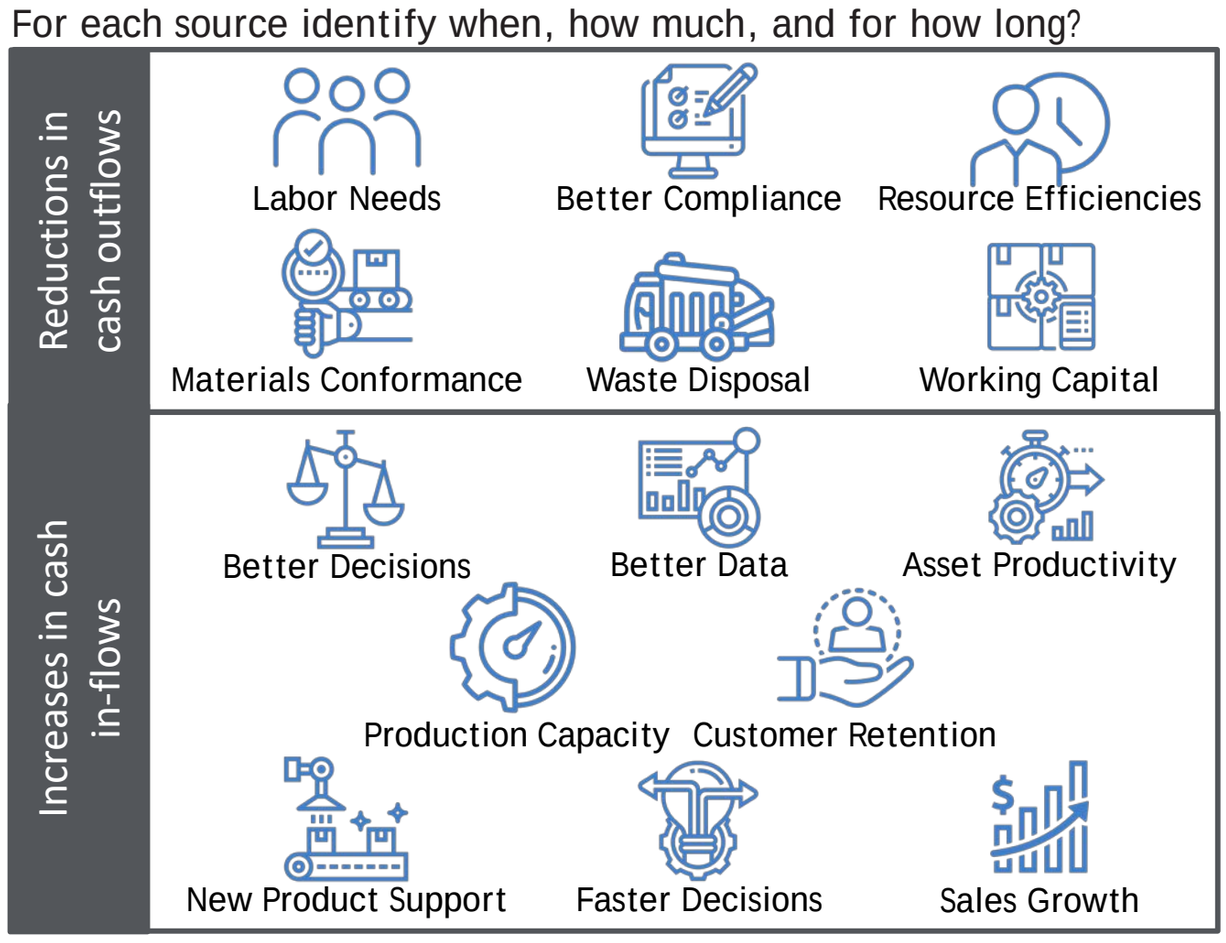
[1] ISPE GAMP Good Practice Guide: Manufacturing Execution Systems – A Strategic and Management Approach, ISPE 2010

NPV Cash Flow Example



Quantify each cash flow

For each source identify when, how much, and for how long?



Consider the Best (Upside) Case and the Worst (Downside) Case

	Category	Downside	Expected	Upside
Project Costs	Hardware expense	$70K	$50K	$40K
	Software cost	$110K	$100K	$90K
	System integration	$340K	$240K	$200K
	Maintenance and support	$18K	$15K	$12K
Cash Flow Sources	Personnel reduced	1	3	4
	Less waste batches	0	1	3
	Improvement in yield (quality)	0.5%	1%	5%
	Improvement in yield (throughput)	0.5%	1%	5%
	Reduction in compliance processing costs	$20K	$60K	$140K
	3 year NPV	**-$75K**	**$834K**	**$3,220K**

Considerations in upside and downside calculations case:

- Challenge your assumptions
- Explore what could go wrong
- Know the risks and determine how to mitigate them
- Consider the timeframe for the NPV: is it too short (or long)

MES Investments can pay off for years

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