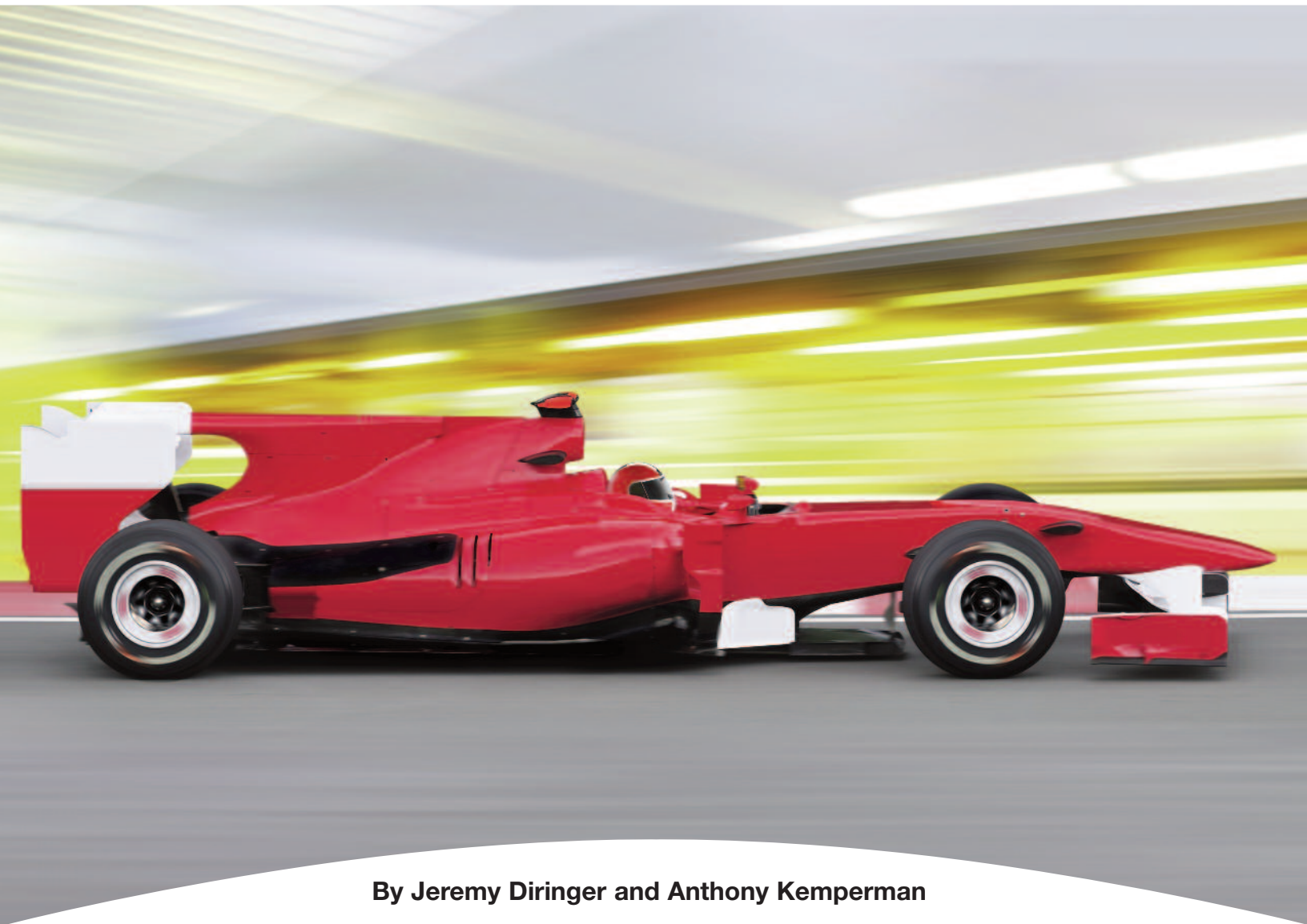


Honeywell Burdick & Jackson® LabReady® Blends



By Jeremy Diring and Anthony Kemperman

The Benefits of Applying Lean Manufacturing Techniques to the Preparation of High-Purity Formulations

Honeywell

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As global competition and cost pressures continue to grow across every industry, many organizations are searching for ways to apply lean manufacturing principles from their production environments to other areas of their operation in order to create a lean enterprise. Using tools such as value stream mapping, sources of waste can be identified and addressed in non-manufacturing areas. As shown in Figure 1, in the world of lean, sources of waste are categorized as inventory, defects, safety, idle time, motion, overproduction and transport. This paper discusses how an organization's adoption of commercial blends as a substitute for in-house high-purity formulations, such as Honeywell Burdick & Jackson® LabReady® Blends, can help reduce waste in the form of motion (productivity), defects (formulation errors), inventory, and safety.

How High-Purity Formulations Are Used

The preparation of formulations using high-purity ingredients applies to a variety of industries, including providers of pharmaceutical, biotech, medical device, process chemistry and environmental testing products and services. Depending on the industry, departments that are tasked with making high-purity formulations can include quality control, research and development, pilot plant, method development and manufacturing areas.

The typical goal of the department making the formulation is to deliver an analytical result. In order to achieve that result, a high-purity formulation is required in the analytical process. To "lean out" this process, a value stream map, as seen in Figure 2, is created to segregate the value-adding steps from the non-value-adding steps. In lean philosophy, value-added steps are those for which a

customer is willing to pay, and everything else is waste. In this case, the customer is willing to pay for the analytical result, and less willing to pay for those steps outlined in Figure 2. As such, an organization should focus on improving or eliminating the formulation preparation process altogether, as it contains a significant amount of waste.

Figure 2. Value stream map of the preparation of high-purity formulations.

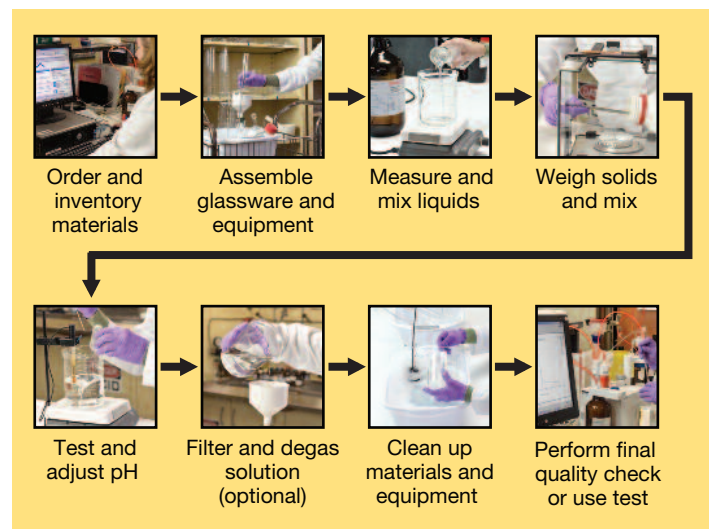
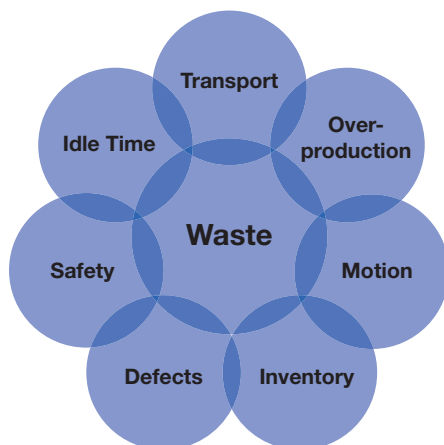


Figure 1. Sources of waste as defined in a lean enterprise.



Productivity and Cost Savings of Commercial Blends

One alternative to making these formulations in-house is to transfer the burden of their preparation to a third party, such as Honeywell Burdick & Jackson. Through its

LabReady Blends line, customers are offered highly customizable blends of high-purity solvents, reagents and buffers that are produced to exact specifications. The major benefit achieved by adopting this kind of commercial blend is the elimination of the non-value-added process steps depicted in Figure 2. The steps that can be eliminated are:

- Assembly of glassware and equipment
- Measuring and mixing liquids
- Weighing solids and mixing with liquids
- Testing and adjusting pH
- Filtering and degassing solution (optional)
- Clean up of materials and equipment
- Performing final quality check or use test

The use of a commercial blend liberates the technical talent required for this process for tackling more value-added activities.

Table 1. Time required for preparing a formulation (Source: Honeywell market study).

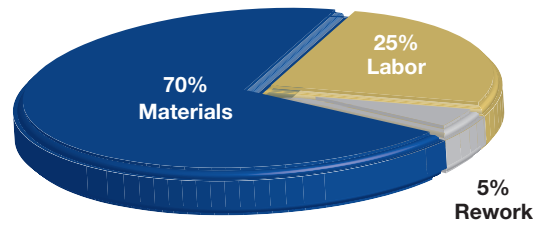
Liquid / Liquid Formulations		
	Average weekly prep time	Average weekly volume
Individual	2.7 hr	7.2 liters
Department	4.9 hr	18.5 liters

Solid / Liquid Formulations		
	Average weekly prep time	Average weekly volume
Individual	3.6 hr	9.8 liters
Department	8.4 hr	33.8 liters

To understand the magnitude of this opportunity, Honeywell conducted a survey of technicians, scientists and chemists who prepare formulations to gain a better understanding of the time it takes to prepare a formulation. As shown in Table 1, the results of this study demonstrate the significant amount of time that is spent each week by individuals and their departments to prepare formulations. For example, a department spends an average of 8.4 hours per week preparing a 33.8 liter formulation consisting of both solid and liquid components.

To assess the wastes and costs associated with the formulation preparation process in more detail, the preparation of a warfarin phosphate buffer was examined. In this analysis, the cost to formulate in-house is compared to that of purchasing a commercially-prepared blend. This example is based on a preparing a four-liter solution five times per week that consists of 27.2 grams of potassium phosphate and 800 milliliters of 2.0N sodium hydroxide, mixed in water with a pH of 7.4 using phosphoric acid¹.

Figure 3. Cost components for preparing a formulation.



When prepared in-house, the formulation cost exceeds \$41,600. As seen in Figure 3, labor and rework resulting from formulation errors represents 30 percent of the total cost. “Leaning out” this process by adopting a commercially prepared blend from Honeywell Burdick & Jackson saves the department more than \$8,000 per year, or nearly twenty percent of the formulation cost. More significantly, 415 hours of manpower in the lab can be redeployed to other technical/scientific tasks, as shown in Table 2.

Table 2. Estimated formulation cost comparison between in-house preparation and commercially-purchased blends (Source: Honeywell market study).

Cost Component of Blend Preparation	Prepared in-house	Purchased LabReady Blend
Raw materials: (~1,000 liters / year)	\$ 29,000	\$ 33,350
Labor to prepare blend: (415 hours / year at \$25 per hour)	\$10,375	\$ 0
<i>Cost of formulation errors (assumes 5% loss rate)</i>		
Raw materials for reformulation:	\$ 1,450	\$ 0
Labor to reblend discarded blends: (20 hours at \$25 per hour)	\$ 519	\$ 0
Waste disposal: (\$2.00 / liter for hazardous waste)	\$ 100	\$ 0
Total annual blending costs:	\$ 41,444	\$ 33,350
Cost saving with LabReady Blends:		20%
Annual productivity gained:		24%



Example: Mobile phase for testing warfarin: 27.2 grams of potassium phosphate and 0.2N sodium hydroxide in water with a pH of 7.4 using phosphoric acid

Safety Benefits

An additional lean benefit that is realized when purchasing a formulation in lieu of in-house preparation is the improvement in safety. In comparison to handling components in their neat format, a commercially-prepared formulation may reduce employee exposure to hazardous chemicals, lower the organization's inventory of hazardous chemicals, and reduce the amount of hazardous waste to be disposed.

The reduction in employee exposure to hazardous chemicals is best illustrated by comparing the various risks, as defined by the NFPA, associated with a neat chemical versus that chemical in solution, also known as the dilution effect. Depending on the chemical, the dilution effect may lower the health, reactivity and/or flammable hazards associated with that chemical. To illustrate this point, the phosphate buffer example discussed above is evaluated in Table 3, where the dilution of sodium hydroxide to a 0.2N solution reduces both the health and reactivity hazard ratings. This exemplifies how eliminating formulation preparation can reduce safety risk, which creates a safer work environment and indirectly lowers costs.

Table 3. Comparison of the NFPA diamond for neat sodium hydroxide versus 0.2N sodium hydroxide solution.

	Sodium hydroxide (NaOH)	0.2N NaOH solution
Used when	Preparing formulations	Handling a commercially prepared formulation
NFPA hazard classification		
Blue (Health)	3: Exposure could cause serious injury even if treated	1: May cause irritation; minimal residual injury
Yellow (Reactivity)	1: May become unstable at elevated temperatures and pressures, may be mildly water reactive	0: Stable

Conclusion

As organizations are challenged to become more efficient without sacrificing effectiveness and safety, the lean manufacturing toolbox is a valuable resource to identify sources of waste. The laboratory's main objective is to generate data, and formulations play a supporting role in achieving that goal. However, many of the steps required in the formulation process can be considered non-value added. The adoption of commercially-prepared high-purity formulations can nearly eliminate all the non-value-added steps, which provides a significant positive impact on a laboratory's productivity, costs and safety.

For more information on Honeywell Burdick & Jackson LabReady Blends, visit www.labreadyblends.com.

References

1. *United States Pharmacopeia 34. Warfarin Sodium / Official Monographs*, pg 4594-4595

Honeywell Burdick & Jackson®

Honeywell Corporate Headquarters
101 Columbia Road
Morristown, NJ 07962

Toll-free in U.S.

Technical Service: 800-368-0050

Customer Service: 800-322-2766

www.honeywell.com/burdickandjackson



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