One thing you can do immediately to reduce human errors

by Sarah Boynton, MBA

3 PATHS TO IMPROVEMENT:

GOOD

- Have an SOP or work instruction that details the level of housekeeping required daily, weekly, and monthly
- Perform monthly walkthroughs
- Assign ownership of each room to an individual
- Recognize teams with consistently clean and organized areas

BETTER

- Create housekeeping checklists
- Implement visual management systems, such as color coded bins
- Keep spill kits stocked and available
- Perform joint weekly walkthroughs with QA and MFG management
- Award teams with consistently clean and organized areas

BEST

- Create housekeeping checklists for all areas of the facility, not just MFG (i.e. warehouse)
- Display pictures of the final state of the room upon exit, so employees can visibly recognize a gap in expectation
- Include EHS in weekly walkthroughs
- Invest in 5S training and support suggestions for housekeeping improvements

Humans are flawed

Gordon Ramsay must have been talking about our industry when he said, "My gran could do better! And she's dead."

I'm talking about housekeeping. When you walk into your manufacturing cleanrooms, do the words "clean" and "organized" come to mind? If not, why? Dirty and unorganized cleanrooms can be a glaring *error trap* in the world of Human Performance. But before we dive further into why, and what an error trap is, we first need to understand how our brains work.

Contrary to what many people believe, humans aren't wired to process multiple things at once and be successful, yet we're often expected to in the workplace. Each of us are gifted a finite amount of cognitive capacity, that's the amount of processing our brains can handle at any particular moment. Everyone has a different amount.

Imagine it like a video game life meter. Each morning you start with a full meter. When it is full, you are functioning at peak performance, but the lower the meter goes, the harder it is to be successful. During the day, the demands placed on your cognitive capacity, known as cognitive load, drain the meter. A few examples include being sick, being anxious or fearful, being introduced to new learning, engaging in training, dealing with complex or confusing documents, and working in disorganized environments. These experiences require the brain to work harder to get the job done. And let's face it, manufacturing work is stressful and riddled with critical steps where technique and precision are vital. Since we aren't computers that can remain plugged in at 100% all day, eventually our brains become tired. *Ultimately, it is more difficult and takes more effort to make the right decisions, take the appropriate actions, and engage with our coworkers.*

That brings us back to error traps. Error traps are factors that impact the capability of someone to complete a task. They are often categorized using the acronym:

TWIN = Task demands, **W**ork environment, **I**ndividual capabilities, and (human) **N**ature

It's why you may have found yourself turning down the music when driving somewhere unfamiliar; the music or podcast you were listening to was fighting for some of your brain's processing power. How many deviations or non-conformances are labeled as "inattention to detail." We might as well change it to "cognitive overload." If you look to the work environment the individual was in at the time of the event, it was likely riddled with distractions and/or interruptions. Does that mean the individual is not at fault? I won't go into this loaded question right now, but if we understand how the brain works, then it's our duty to recognize error traps and set ourselves up for success.
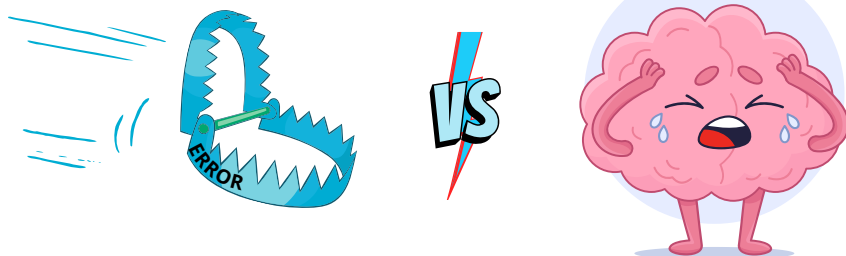
No matter how much we think we can focus in a dirty and disorganized environment, our brains tell us otherwise. Scientists at the Princeton University Neuroscience Institute have used fMRI and other approaches to show that our brains like order. They determined that constant visual reminders of disorganization drain our cognitive capacity and reduce our ability to focus. You don't want your work environment working against you; it should contribute to fostering the right behaviors. Anticipate error traps.

Did you know your brain makes up only 2% of your body mass, however it uses 20 percent of your oxygen supply and depends upon 20 percent of your blood flow? What a needy little organ!

Source: Smithsonian Institution

For example, if the expectation for the team is to perform surface wipe downs at the end of the shift, then each cleanroom should have a regularly stocked, designated location for cleaning materials to be stored and maintained. If employees continuously have to hunt for materials to do the job, especially at the end of a shift, their tired human brain will have an easier time rationalizing the idea of cutting corners. *Remember this: you cannot change the human condition of your employees, but you can control the conditions under which they work.*

Good Housekeeping: Where to Start

According to Mark Paradies, co-creator of the TapRooT®System for analyzing human error, cleanroom design can aid or inhibit housekeeping efforts. Implementation of proper storage, lighting, temperature, and waste handling practices for each area, will help prevent issues like cross-contamination and material mix-ups. *In addition to the design, good housekeeping also involves a consistent vigilance among all entering the area to maintain it to the defined standard.*
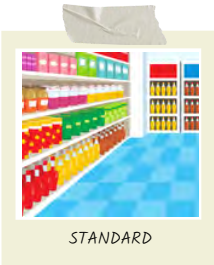
Take for example, shared spaces like gowning or material airlocks. Emptying or taking the shared materials and failing to replenish them, can lead to the inappropriate movement of people and materials into the cleanrooms. Over time and continued absence of supplies, a new norm is created, and disinfection is inconsistently performed. You may see an uptick in environmental monitoring findings, or worse, lose a batch to contamination.

STANDARD

Consider another example:
Plant A: the shared cold room houses multiple samples, product, and prepared solutions required for both upstream and downstream processing. Containers are labeled and stored on shelving, but there is no segregation between batches, manufacturing teams, or materials. If it fits, it sits.
Plant B: the shared cold room shelves are labeled by color and material type. Specific areas are dedicated to each team, so material will always be placed in the same location. Also, the prepared solutions for the upstream process are in a different color container than the downstream solutions.

Which cold room has more error traps? What are they?

Table 1: Common Error Traps (TWIN)

Task Demands	**Individual Capabilities**
• Repetitive actions • Lack of, or unclear standards, goals, or responsibilities • Interpretation requirements • High workload • Time pressures	• Unsafe attitudes • Imprecise communication tools • Inexperience / lack of proficiency • Illness or fatigue • Indistinct problem solving skills
Work Environment	**Human Nature**
• Unexpected equipment conditions • Confusing displays & controls • Distractions & interruptions • Workarounds • Personality conflict	• Habit patterns • Complacency or Overconfidence • Stress • Assumptions & inaccurate risk perceptions • Mindset

As management and quality professionals, the best place to begin your efforts in improving housekeeping is on the manufacturing floor.

Perform walkthroughs and talk to the people who use the rooms every day!

What do they need to meet the standards and expectations for housekeeping? Ask questions, don't assume. Empower them to escalate their ideas for making the rooms more organized and *do not let continued escalations fall on deaf ears.*

Doing so can be a contributing factor of "presenteeism," which is when employees are physically at work, but their brains have 'checked out.' Talk about an error likely situation. During your walkthroughs, tell people when they're doing a good job. In a recent study by Harvard Business Review, the results around employee engagement with respect to recognition were staggering. Leaders rated in the bottom 10% for providing recognition had an average employee engagement of 27%. This was far off from the 70% average employee engagement seen under leaders in the top 10% for providing recognition. While "good job" is better than saying nothing, try to frame the feedback in a specific way and in a group setting. *Focus on reinforcing the behavior or situation you expect from everyone. Adding the why is a bonus.*

Instead of this…. Good job!

Say this… Good job emptying the waste bin regularly, so it doesn't overflow or lead to people pushing their hands into it when disposing of waste. This is very important for contamination control.

For individuals who are regularly working in dirty or disorganized areas, start taking small steps to instill good housekeeping habits. This is mainly fostered through action; if you are in a room with 4 people and you start performing wipe downs during a long chromatography step, the other 3 people most likely won't sit back. If they do, bless their hearts. Next, work with your management to clearly outline what is working or not working and come with some ideas. Is it hard to keep things organized because of space? How can you utilize carts or other locations to create a Kanban of tools or materials? Talk to your coworkers in other departments; is there something working for them that you can implement? It would also be useful to get educated on the 5S principles that have made many high reliability organizations function so well. There are several offerings online or you can work with your organization to ensure everyone at the site is knowledgeable on these concepts, for more lasting impact. Lastly, you can implement a daily or weekly housekeeping checklist that is owned among members on the team. *I have provided a sample checklist at the end of this document, that can be used right away or as inspiration for your specific needs. I recommend laminating and keeping in each room, to be completed by the area owner at the end of each shift.*

Final Thoughts

Good housekeeping is the one thing you can do immediately to reduce human errors. Recognize and award those that help in these efforts. Probably the most important points to understand is that if housekeeping is not part of the job and built into the schedule, it will only get done to the level time allots. *And while it is everyone's responsibility to maintain good housekeeping efforts, it is up to your leaders to not only set the standard, but ensure it is consistently being met.* Go take the time to clean and organize your areas. This will reduce cognitive overload and mitigate error traps that are waiting to be activated. Then watch as the "inattention to detail" deviations fade away.

One thing you can do immediately to reduce human errors

So, what does good housekeeping look like? Check out the remaining article for more details.

What good housekeeping looks like	What not-so-good housekeeping looks like
A housekeeping SOP details the expectations for each area: This doesn't have to be a 20 page document. Work instructions and checklists go a long way for standard daily, weekly, or monthly tasks. Also consider how you want to manage spills, cosmetic issues, and other concerns and add these instructions so there is a consistent approach across the plant.	*No SOP in place, and teams maintain their areas the way they want:* Inconsistent housekeeping practices among teams can lead to animosity. Everyone should be held to the same standard and it must first be defined.
Management performs regular walkthroughs: Providing an effective level of supervision is critical for reliable operations. Immediate recognition of a gap between procedures and actual practice helps prevent poor habits from spreading like wildfire, or Normalization of Deviation. Anyone who watches or plays sports know the better teams typically have a better coach. Someone who is observing and correcting to the expectation real time, not once a month. Observation and coaching should be at the top of list for manufacturing and QA management's roles and responsibilities. I will have more on coaching in another article!	*Limited oversight:* If months go by and your management or quality hasn't performed a walkthrough and assessment of housekeeping practices, you miss out on great coaching moments. Not only that, but complacency can begin to set in.
A place for everything, and everything in its place: This approach is the foundation of the Toyota Production System and 5S/lean six sigma. It fosters organization. Understanding what tools you need to perform each task and where in the room they are used, helps in defining a designated location where they should remain when not in use. The tools are always available when you need them, and clearly evident when missing. Shadow boards are a great option, but even simple demarcation lines with tape is a start. At the end of each shift, an individual should be assigned responsibility to verify everything is in its place.	*Tools have no designated location and are transferred between rooms:* An alarm sound should be going off in your head. Tools that don't have a home are more likely to contribute to contamination and cross-contamination events, as they are passed between process steps. In addition, it will be difficult to trace the movement of small equipment and tools when investigating events, especially if movement is not required to be documented.
Surfaces are disinfected after each use: IPA is your friend and is rapidly antimicrobial against bacteria, fungi, and viruses. Frequent disinfection strengthens the technique for proper wiping, using unidirectional overlapping strokes, and reinforces the overall habit.	*Some surfaces are disinfected, while wheels, shelves, and the undersides of tables and carts are not:* These frequently missed locations can be forgotten sources of contamination. Visual cues in areas where carts are used can help remind people to spray down the wheels and undersides.
Materials and tools are organized in cabinets or shelves, kits, or Kanban locations until time of use: Have a system, whatever it may be, and stick to it. Labeled acro bins on shelves can do wonders for organization. Also, ensure there is an owner for any area that requires stocking. Your brain will thank you for keeping items available and in the same place every time.	*Materials are stored on top of cabinets and equipment:* This behavior creates safety issues, as well as impacts cleanability. Some single use materials can become damaged from improper storage. The probability of finding or using expired materials is also greater. If you are seeing this happen frequently, you may want to revisit the intervals at which items are being issued.

What good housekeeping looks like	What not-so-good housekeeping looks like
Nothing is on the floor that shouldn't be there: Aside from being a safety issue, tubings, equipment, waste, and other materials on the ground impact 2 other important aspects of manufacturing: contamination control and perception. The floor is the dirtiest place in the room and is especially hard to effectively clean if there's something on it around every corner. In addition, clutter on the floor and poor hose organization is indicative of a questionable GMP culture to outsiders, like inspectors or clients. Check out a newer product on the market for managing hoses and tubings here.	***Tubings, equipment, waste, etc. can be found on the floor:*** This type of behavior is almost always the result of deficiencies in the culture and/or management. Lower level manufacturing technicians, especially new ones, will rarely go out of their way to correct those above them. If they see their trainer or manager leave waste or tubing on the floor, it will be taken as acceptable behavior. Even if they know it is poor practice. As humans we want to be liked and accepted. *It is easier to be wrong with the crowd than right alone.*
Damage to insulation, equipment, walls, and other cosmetic issues are escalated and mitigated in a timely manner: Part of your daily or weekly housekeeping efforts should include checking out the fit and function of your room. Are there any process lines leaking or looking a little ragged? Do you see gashes in the wall or holes in the ceiling? Is there rust or rouging on equipment? Promptly recognizing and dealing with these issues will aid in contamination control and unexpected equipment downtime.	***Damage to insulation, equipment, walls, and other cosmetic issues are left untreated until the last minute*** (i.e., audit time): This is asking for trouble. Some issues may require lengthy fixes, and be left as an eyesore during an inspection or client audit. Damaged insulation or equipment can also pose a safety threat.
Equipment, opened containers, and in process materials are labeled: Labeling, like many housekeeping efforts, is a habit. If it is practiced and done regularly, the brain will make sure it's done, even if you're on autopilot. Setup the environment to foster labeling by ensuring markers and pens are available, status tags are plentiful, and keep the process simple. Take a risk-based approach when determining what needs labeling when, and to what level.	***Equipment, opened containers, and in process materials are inconsistently labeled:*** Failing to label equipment status or the contents of a container can cause serious injury. I remember early on in my career hearing a story about an employee that was hospitalized after opening a tank that was still in use but labeled "Empty." Labeling had been performed, but not consistently, leading to an unfortunate situation. Clear and accurate labeling practices will minimize cognitive load and help prevent errors such as incorrect testing of samples or use of the wrong material or equipment.
Waste bins are emptied and airlocks are free of trash: Managing the control of waste, especially when manufacturing viral vector therapies is critical to preventing contamination and cross-contamination events.	***Waste bins are emptied and airlocks are free of trash:*** Not only do the behaviors around bagging and handling of waste need to be clear, there should be an understanding as to when to use a biohazard bag vs. regular trash. Lastly, overflowing trash bags are notorious at fostering the behavior of pushing down waste with our gloved hands, both a safety and contamination risk.
Documentation is reviewed before end of shift: Don't forget about your GDPs. This is what makes all your efforts in the cleanroom mean something, because as you know, if it wasn't documented, it didn't happen. Logbooks, processing records, and other documentation that was used during the day should be reviewed for completeness before leaving. If multiple processing records are in play, set up a filing system that is color coded to ensure data is recorded in the correct location.	***Documentation is reviewed at the end of the process:*** By not performing regular reviews of documentation, underlying issues can go unchecked past the point of no return. Missed entries and unclear information can lead to nuisance deviations and unnecessary CAPAs. Build in the time during the workday to perform reviews, and if you want to go the extra mile, have your management and QA perform a review as well. Reminder: the value of document review will be commensurate with how well you train people on the review process.

About the Author:
With over 13 years of manufacturing and training expertise, Sarah and BSCS, LLC bring high value support to your business needs. For more information please reach out to Sarah.Boynton@bscspartner.com

Thank you

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HUMAN PERFORMANCE

HOUSEKEEPING CHECKLIST

Performed throughout the shift, and verified as complete by area owner.
Escalate any concerns immediately, and add to the comments section for next shift awareness.

GENERAL

- [ ] Clean tables and carts, incl. undersides and wheels
- [ ] Empty used or expired solutions
- [ ] Clean up any standing liquid or spills
- [ ] Disinfect drains
- [ ] Verify floor is free from tubing or other items
- [ ] Verify in process tubing is not kinked or leaking
- [ ] Organize and review documentation
- [ ] Review and replace logbooks
- [ ] Store chemicals in the appropriate location
- [ ] Verify incubator or refrigerator doors are secure
- [ ] Empty & replace garbage/biohazard
- [ ] Verify airlock is free of clutter and waste
- [ ] Inspect walls, ceilings, and floor for damage

EQUIPMENT

- [ ] Clean exteriors; verify no leaks on active units
- [ ] Verify no active alarms
- [ ] Check connections (clamps, quick connects, etc)
- [ ] Inspect for damage, rust, or rouging

FLIP ⟶

MATERIALS & TOOLS

- ☐ Restock materials (gowning, solutions, single use, etc.)
- ☐ Remove expired items
- ☐ Verify next shift has required materials
- ☐ Clean and organize tools
- ☐ Verify hoses are stored appropriately, if applicable
- ☐ Verify in process solutions are stored at the right temp.

OTHER

- ☐ _____
- ☐ _____
- ☐ _____

Comments:

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Verification performed by
(initial/date): _____

Contact:

Add emails or phone
numbers of the people to
call if escalation is required