Chance Meeting …

Fellow Members,

Throughout our lives, we all have countless, chance encounters in our personal and business lives. We never know where, when, or who we may meet that may change the direction of our lives.

During my lifetime I have had many of these chance meetings, and unfortunately while feeling the pressure of our hectic lives we do not embrace the opportunity that has fallen into our laps. However, sometimes we do, and we cherish those chance meetings for the rest of our lives.

I have experienced both of these in my personal and professional life. The first was in my personal life, when I was asked by a friend to accompany him to another friend’s wedding. After a nice dance with my date, we went to the refreshment stand (OK, the bar). Another young gentleman, Dennis Berger, accidentally tripped on my long formal dress after he picked up his drink (as you can tell, it was in the 1970s). After tearing the bottom of my dress, Dennis spent the next several hours apologizing to me. Well, to make a long story short, he asked me out on a date about a month later and yes, we eventually got married.

Professionally, I remember the day that I ran into one of my old bosses whom I had not seen for several years. We had casual conversation and then he asked me what was going on with my career. He knew I had taken a couple of years off to be home with my son, and just as he thought, I really did want to work again. He had just run into a friend who was looking for a new assistant, so I called his friend and started to work one month later on 8/8/88. I have worked with this person at three different companies for the past 28 years, and his support has allowed me to grow and develop my career into something that I enjoy each and every day!

In 2008, I also went to the ASQ World Conference on Quality and Improvement with my company, a certification body. My company always had some type of fun activity in our booth, and that year we had a prize wheel. We had some great giveaways based on where the wheel landed. The vice chair of the ASQ FD&C Division really wanted to win one of our umbrellas (OK, we gave him five chances to win!). During those many attempts, we struck up great conversation about the FD&C Division, and eight years later the friendship is strong and I am now the chair of the FD&C. This chance meeting has led me to be a part of this great group of people.

My words are just to encourage you to take the opportunities that come out of those chance meetings. Sometimes they will inspire you for the day, sometimes for a lifetime!

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The U.S. Food and Drug Administration today issued a final rule establishing that over-the-counter (OTC) consumer antiseptic wash products containing certain active ingredients can no longer be marketed. Companies will no longer be able to market antibacterial washes with these ingredients because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections. Some manufacturers have already started removing these ingredients from their products.

This final rule applies to consumer antiseptic wash products containing one or more of 19 specific active ingredients, including the most commonly used ingredients—triclosan and triclocarban. These products are intended for use with water, and are rinsed off after use. This rule does not affect consumer hand “sanitizers” or wipes, or antibacterial products used in health care settings.

“Consumers may think antibacterial washes are more effective at preventing the spread of germs, but we have no scientific evidence that they are any better than plain soap and water,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research (CDER). “In fact, some data suggests that antibacterial ingredients may do more harm than good over the long-term.”

The agency issued a proposed rule in 2013 after some data suggested that long-term exposure to certain active ingredients used in antibacterial products—for example, triclosan (liquid soaps) and triclocarban (bar soaps)—could pose health risks, such as bacterial resistance or hormonal effects. Under the proposed rule, manufacturers were required to provide the agency with additional data on the safety and effectiveness of certain ingredients used in over-the-counter consumer antibacterial washes if they wanted to continue marketing antibacterial products containing those ingredients. This included data from clinical studies demonstrating that these products were superior to non-antibacterial washes in preventing human illness or reducing infection.

Antibacterial hand and body wash manufacturers did not provide the necessary data to establish safety and effectiveness for the 19 active ingredients addressed in this final rulemaking. For these ingredients, either no additional data were submitted or the data and information that were submitted were not sufficient for the agency to find that these ingredients are Generally Recognized as Safe and Effective (GRAS/GRAE). In response to comments submitted by industry, the FDA has deferred rulemaking for one year on three additional ingredients used in consumer wash products—benzalkonium chloride, benzethonium chloride, and chloroxylenol (PCMX)—to allow for the development and submission of new safety and effectiveness data for these ingredients. Consumer antibacterial washes containing these specific ingredients may be marketed during this time while data are being collected.

Washing with plain soap and running water remains one of the most important steps consumers can take to avoid getting sick and to prevent spreading germs to others. If soap and water are not available and a consumer uses hand sanitizer instead, the U.S. Centers for Disease Control and Prevention (CDC) recommends that it be an alcohol-based hand sanitizer that contains at least 60 percent alcohol.

Since the FDA’s proposed rulemaking in 2013, manufacturers already started phasing out the use of certain active ingredients in antibacterial washes, including triclosan and triclocarban. Manufacturers will have one year to comply with the rulemaking by removing products from the market or reformulating (removing antibacterial active ingredients) these products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by helping to ensure the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for helping to ensure the safety and security of our nation’s food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

The FD&C Division relies on the support of its members to be successful and to ensure that the voices of the food, drug, and cosmetic industries are heard. Are you interested in becoming more involved in the division? Please contact Rosemarie Christopher at rosechristopher@medexecintl.com.
ASSESSMENT OF PARTICULATE MATTER IN SOLID ORAL DOSAGE

Michele Pruett, President and Principal Consultant at MLP GXP Solutions LLC

Proper assessment of particulates found in solid oral dosage forms is a critical component to ensuring the safety and efficacy of drug product. There is clear compendial direction and guidance available to evaluate particulates in parenteral products because of the high risk to patient safety; particulate matter introduced into the bloodstream can cause serious adverse reactions.

Conversely, there are no similar specific requirements for oral products as dosage forms intended for digestion are of lower patient risk. The FD&C Act Sub V Part 501 A § 351 is clear that a drug or device shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance. However, filthy, putrid, or decomposed substances (garbage, waste, excrement, rotting or decaying material) are not generally what we encounter in the modern pharmaceutical environment adhering to cGMPs. Active Pharmaceutical Ingredient (API) and excipient manufacturers have made efforts to outline what can be expected from a chemical manufacturing perspective. However, it is ultimately the responsibility of the quality control unit dispositioning the drug product to ensure that adequate investigation and evaluation consistently is carried out when particulate matter is identified.

Scope

In oral solid dosage and its components, particulate matter of significance is limited to visible particles, as minute particulate matter generally passes through the gastrointestinal tract without incident. The FDA Health Hazard Evaluation Board evaluated reported cases, both injury and non-injury, of foreign objects in food. The board found that foreign objects that are less than 7 mm maximum dimension rarely cause trauma or serious injury, except in special risk groups such as infants, surgery patients, and the elderly. It is important to differentiate particles from impurities, whose content, qualification, and control are established under ICH Q3A-D. The chemistry and safety aspects of organic impurities, inorganic impurities, and residual solvents are evaluated, addressed, and acceptance criteria (specifications) created to ensure the quality of the products as part of NDA.

Types of Particulate Matter

In order to align with the compendial language used for parenteral products, the following categories will be used: extrinsic (from outside the process); intrinsic (from within the process); inherent (part of the process / formulation). Extrinsic particles such as hair, insect parts, paint, rust, pens, personal identification badges, and tape pose the greatest risk. Intrinsic particles from processing equipment, primary packaging (e.g., stainless steel, glass, rubber, silicone oil, Teflon, Viton) or support equipment (e.g., scoops, cleaning tissues, personal protective equipment like gloves, clothing, textiles, gowning gear, or filter masks) are less of a risk as they are composed of materials intended to contact the product and were selected for their compatibility with the process and cleaning conditions. Inherent particles such as agglomerates (possibly discolored)—fine pieces of material whose source is intrinsic to the supplier’s formulation or process—present the lowest level of risk.

Strategy

From a quality perspective, the goal will always be 100 percent particle free through the implementation of good manufacturing practices; however, as no process has been shown to be completely closed, clean, or produce zero defects, we must be prepared to manage particles as they are observed. IPEC introduced the concept of technically unavoidable particles in 2015. Some examples of these would fall into the intrinsic particle category: materials shed from equipment during normal use; particles consistent with ancillary components that are expected to wear (seals, gaskets, filters); discolorations due to lubricants; oils or greases used on the equipment; and particles shed from packaging components. Others may be inherent to the process: compacted or agglomerated particles; elongated or tangled particles; flakes; under-processed materials; color variation normal to the product; particles expected from natural products (e.g., wood pulp or mined materials); or charred particles. No matter the source, it is essential that firms have a strategy for what steps are required when particles are encountered.

It is crucial that when particles are observed, the assessment process begins immediately with notification to the quality control unit. The quality control unit can then ensure the material is contained and determine the scope. Representative samples can be collected and evaluated. Prior to submitting samples for forensic characterization, investigation of possible in-process sources should be evaluated. The following should be reviewed to identify potential sources of the particle(s):
• Processing and ancillary equipment should be inspected for wear or shedding
• Processing room(s)
• Packaging materials
• Cleaning logs
• Batch records
• Procedures followed in the course of the processing should be reviewed with the personnel that carried them out
• Raw material documentation
• Historical review of any particles associated with the process or materials involved

If a potential source is identified but cannot conclusively be confirmed, samples should be taken, as feasible, and presented with the particle samples for forensic analysis. Providing samples of possible sources to the laboratory for comparative analysis or alternatively providing them with the product contact materials allows the forensic laboratory to provide confirmative identification rather than a list of possibilities. Based on the forensic characterization results, the investigator can return to the review and exhaustively evaluate the potentials for introduction of particulate matter.

Assessment
Once the particle(s) is identified, categorized, and most likely source identified, assessment of how the particle(s) was introduced is required. If the likely source is the oral solid dosage manufacturing, then the investigation should include a discussion of (as appropriate to the identified particle):

• The complete finished dosage manufacturing process
• Equipment train maintenance, condition, and cleaning
• Lubricant controls in equipment
• Material handling practices, including the packaging of receipt or holding containers and the mode of addition
• Personnel practices
• In-process inspections and testing (including metal detectors)

Conducting historical evaluation of the finished product, including defect rate for the visual inspection, is also an important component of a thorough investigation. Further investigatory work, such as visual inspection, crushed tablet/ open capsule inspection, and disintegration evaluation for insoluble particulate matter, may be warranted if a trend is evident. Based on forensic characterization of particulate matter and relative percent defective in finished good lot(s), the assessment may also require a health hazard evaluation.

In the event that the particle originates from the components3 or API, a similar investigation needs to take place with the supplier, including (but not limited to):

• Details of the process or reprocessing
• Details of any particles that may be inherent to the raw materials (e.g., natural products, mineral mining, color variation)
• Equipment—train maintenance and cleaning
• Washing, rinsing, and lubrication controls
• Discussion of the potential for material charring and how this is controlled
• Discussion of the potential for morphologically distinct particles1 (misshapen—flakes, tangled, elongated, agglomerated, compacted)
• Material handling and inspection of raw materials (including packaging), in-process, intermediates, and final product
• Personnel practices
• In-process monitoring or testing
• Any enhancements or corrective/preventive actions they have taken to reduce particulate matter such as
  ▶ Design of plant, process, and equipment
  ▶ Plant and equipment maintenance and cleaning
  ▶ Removal/Detection methods
  ▶ Inspection methods
• Statements of what particulate level can reasonably be considered inherent in the final material

Particle Evaluation
Particle evaluation is multifaceted and depends on the depth of experience with the product. It is important to ensure that it is complimentary to the investigation rather than the basis of the investigation. Any potential sources identified by the assessment should be sampled and evaluated alongside the particulate matter sample. Forensic evaluation of particles may include:

• Visual comparison to potential sources
• Microscopic comparison
• Assessment against previously identified defects
• Compositional analysis such as
  ▶ Infrared microscopy
  ▶ Scanning electron microscopy
  ▶ Energy dispersive x-ray spectrometry
  ▶ Polarized light microscopy
  ▶ Stereomicroscopy

Corrective and Preventive Actions
Regardless of the source, the root cause or causal factor for the entry of the particle(s) needs to be identified. As with all investigations, corrective and preventive actions must address the root cause. The goal of these actions and continuous improvements being to reduce the occurrence of finished dosage rejects due to particulate matter to zero.

Elements for consideration:

• Design of building, facility, and traffic flow
• Facility maintenance and cleaning
• Equipment selection, maintenance, and cleaning
• Protection of exposed product
• Appropriate gowning procedures
• Effective training of operators and maintenance staff
• Adequate procedures for the control and handling of components3
  ▶ Sampling
  ▶ Storage
and intended use is a key element to ensuring the relationship between the type of particle, risk, and intended use is a key element to ensuring the safety and efficacy of drug product. Having a strategy in place to consistently assess, investigate, and evaluate observed visible particles is essential in order to reduce finished dosage rejects due to particulate matter to zero. Understanding the relationship between the type of particle, risk, and intended use is a key element to ensuring the safety and efficacy of drug product. Having a strategy in place to consistently assess, investigate, and evaluate observed visible particles is essential in order to reduce finished dosage rejects due to particulate matter to zero. Understanding the relationship between the type of particle, risk, and intended use.

**REFERENCES**

1. 2015 The International Excipients Council (IPEC) Technically Unavoidable Particle Profile (TUPP) Guide.
2. June 2015 Active Pharmaceutical Ingredients Committee (APIC) APIC Guidance on Handling of Insoluble Matter and Foreign Particles in APIs.
3. 21 CFR 210.3 Definitions
   - (3) **Component** means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.
   - (5) **Fiber** means any particulate contaminant with a length at least three times greater than its width.
   - (7) **Active ingredient** means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.
   - (15) **Quality control unit** means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

(20) **Acceptance criteria** means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(21) **Representative sample** means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to ensure that the sample accurately portrays the material being sampled.

5. 1993 October Guide to Inspections of Dosage form Drug Manufacturer’s – CGMPRs.

3. **Particulate Matter Testing**
   - Particulate matter consists of extraneous, mobile, undissolved substances, other than gas bubbles, unintentionally present in parenteral solutions.
   - Cleanliness specifications or levels of nonviable particulate contamination must be established. Limits are usually based on the history of the process. The particulate matter test procedure and limits for LVPs in the U.S.P. can be used as a general guideline. However, the levels of particulate contamination in sterile powders are generally greater than in LVPs. LVP solutions are filtered during the filling operation. However, sterile powders, except powders lyophilized in vials, cannot include filtration as a part of the filling operation. Considerable particulate contamination is also present in sterile powders, which are spray dried due to charring during the process.
   - Review the particulate matter test procedure and release criteria. Review production and control records of any batches for which complaints of particulate matter have been received.
   - **Production Records**
     - Production records should be similar to those for other dosage forms. Critical steps, such as integrity testing of filters, should be signed and dated by a second responsible person.
     - **Review production records to ensure that directions for significant manufacturing steps are included and reflect a complete history of production.**

**Conclusion**

Effective management of particles observed in solid oral dosage, and its components, is a critical component to ensuring the safety and efficacy of drug product.
MY WORLD CONFERENCE JOURNEY

As the Region 14 regional counselor, Tim Parrent was awarded one of two stipends (to help defray the registration costs and related expenses) to attend the preconference training at the World Conference on Quality and Improvement. Here is a brief update about his experience.

There is nothing quite like starting a trip—for business or pleasure—with flight delays and issues before you ever really get started. And that is how my journey to the World Conference began. Fortunately, I was scheduled to arrive late afternoon, so the later evening arrival was not too bad. Check it up to good planning on my part.

My good planning only lasted until I got to my hotel. I realized I did not know where or when the ASQ Member Leader Training was the next morning. I sent out a few texts and emails to colleagues who were attending the conference and found out the training started at 7:00 a.m. Yes, that’s right! It started at 7:00 a.m. on a Saturday morning, which meant I needed to get there early enough to register and collect my training materials. Fortunately, there was coffee and food. It also helped that I am generally a morning person. As I was feeling pretty good and relaxed, my brain was on overload from all the new things at the ASQ networking session at the Harley Davidson Museum. It is fascinating to see the history of such an iconic product as Harley Davidson—how the product line has evolved through the quality design, innovative features, and strong brand image over the years.

On Monday the first full day of the conference and it started off “freaky,” as in with Stephen Dubner, author of the books Freakonomics, SuperFreakonomics, and Think Like a Freak. There were multiple tracks with great speakers throughout the day and more time at the exhibit hall working the booth and checking out all the other exhibits. The FD&C Annual Business Meeting was held at the end of the day and was open to any FD&C member. Multiple reports and updates were given as well as some well-deserved recognition to some very hard-working members. We ended the day with an incredible FD&C riverboat cruise and dinner, which provided a great venue to relax and build relationships. This photo was taken as we were heading back in. Downtown Milwaukee is beautiful at night.

On Tuesday Liz Wiseman, author of Multipliers and Rookie Smarts, shared key concepts from her research of “why learning beats knowing in the new game of work.” This provided the fuel for many conference attendees to learn new things all day Tuesday. The afternoon keynote speaker was Brian Little, psychologist, scholar, and author, who shared content from his book Me, Myself, and Us: The Science Behind the Personality and the Art of Well-Being. He invited the audience to take a quiz to see where they fit on the introvert/extrovert spectrum. We continued to learn new things at the ASQ networking session at the Harley Davidson Museum. It is fascinating to see the history of such an iconic product as Harley Davidson—how the product line has evolved through the quality design, innovative features, and how it has maintained such a strong brand image over the years.

Wednesday was the last day of the conference and it was packed with more sessions across multiple focus areas and levels. We ended the conference with the closing session, which included the International Team Excellence Awards ceremony and keynote speaker Josh Linkner. ASQ Headquarters also offered tours of their offices after the close of the conference. Unfortunately, I had to dash out to catch my flight home. Thankfully, the journey home was uneventful, which allowed time for me to take in all that I had experienced over the last six days.

I am thankful to the division for allowing me to attend and be a part of a great organization.

With much gratitude,
Tim Parrent

Note: The 2017 World Conference on Quality and Improvement is May 1 – 3, in Charlotte, NC.
Update on Computer-Based Certification Exams

Luke Foo, ASQ Exam Subcommittee Member

The computer-based ASQ certification exams are here. The first 10 certification exams that will be rolled out will be for CQT, CQI, CRE, CBA, CHA, CMQ/OE, CSSBB, CMBB, CSSYB, and CSQP. The remaining certifications for CQA, CQE, CQIA, CSSGB, CQPA, CCT, and CPGP will be implemented starting on December 1, 2016.

There will be greater flexibility in scheduling your exam date. You will be allowed to choose an exam date within a three-week window that fits your schedule. There will be about six windows throughout the year. After you apply to take the exam, you will be notified by ASQ to schedule your exam, and select a specific date inside the time window on the Prometric website. The exams can be taken at any of the 8,000 Prometric locations of your choosing.

There will be new test-taking rules that all members should be aware of. The full set of rules can be found on the ASQ and Prometric websites, but I would like to highlight the prominent ones:

1. Items prohibited in the test room: outerwear, hats, food, drinks, purses, briefcases, notebooks, cell phones, watches, written notes, and wallet. Lockers will be provided.
2. Only calculators with numeric keys will be allowed. Calculators with alphanumeric keyboard will not be allowed. Smart phones with calculators will not be permitted.
3. As in the past, exams are open-book. However, there will be one major difference. All reference materials brought into the test room must be bound. Bound is defined as material permanently bound by stitching or glue and materials fastened securely in its cover by fasteners, which penetrate all papers (i.e., ring binders, spiral binders, plastic snap binders, brads, or screw posts). Manually or hand-stapled documents that are not securely fastened in their covers are not allowed.

   (No collections of questions and answers or refresher-course quizzes will be permitted. Reference sources that contain such material must be removed or obscured.)
4. If you do not schedule your exam with Prometric at least five days prior to the start of the exam window you selected, you will be considered a no-show. You will not receive a refund.

Other notable changes are:

- Faster results. Upon completion of the computer-based examination, you will receive a printed copy of your test results. For those who fail, you will be given diagnostic information on your performance.
- The convenience of retesting—the waiting time will be reduced from six months to two months.

Remember to bring identification, which must include English characters/translation, your photograph, and signature.

And lastly, I strongly encourage you to take the demo test in order to familiarize yourself with the look and feel of the test. The demo shows you how to navigate the various buttons. This can save you precious moments during the exam to concentrate on the test questions, and not have to worry about what buttons to press during the exam. The link to the demo test is: www.prometric.com/_layouts/results/index.html.

Please visit the frequently asked questions section of both the ASQ and Prometric websites at asq.org/cert/faq and www.prometric.com/en-us/for-test-takers/prepare-for-test-day/frequently-asked-questions/Pages/default.aspx.

Good luck to all!

Call for Content to Publish in the FD&C Division Newsletter

Please contribute an article for the newsletter that is informative, beneficial to members, enhances knowledge base or industry practices, and helps in research and development.

Suggested topics may include:

- Technical field
- Regulatory affairs/update
- Industry news
- Good practices in workplace/experience worth sharing
- Member achievements/outstanding contribution
- Member suggestions/thoughts
- Quality aspect
- Member suggestions/thoughts

Please submit content (including articles) for potential publication in one of three newsletters published annually.

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