Medical gas compliance trends

The decisions you take to make your own business leaner and smarter ultimately influence regulatory requirements and what are some of the current trends.

The evolution of compliance requirements in the medical gas industry generally derives from two major sources. The first source – the activities of FDA and State regulatory agencies are generally conducted in the open, with the involvement of both the industry members and the public. The whole process of promulgating and introducing new regulations in our industry, while never popular, is generally well understood.

The other major driver of changes in medical gas compliance requirements is evolving industry business practices and technology. How that results in changing FDA requirements is probably less well understood.

Striving for continuous improvement

Both the Food Drug & Cosmetic Act and the good manufacturing practices contained in Title 21 of the Code of Federal Regulations orient drug and device manufacturers towards continuous improvement in their practices and processes. For example the drug regulations require that firms conduct annual program reviews. During these reviews FDA expects firms to assess internally and externally generated information and determine potential compliance issues and trends related to their business.

The basic purpose of these reviews is to facilitate the firm's management in understanding any potential compliance related issues associated with their manufacturing operations, and for them to then authorize any needed actions or changes to eliminate potential issues. Similarly, FDA device regulations require firms to conduct annual internal audits, with the results of these audits to serve as potential improvement actions. As drug and device firms make these internal corrections and improvements to their compliance practices they become the new, or current, good manufacturing practice. This is the basic origin of the term "current good manufacturing practices" or cGMP.

Over all the years and all the audits we have done, for firms in virtually every segment of the medical gas industry, there are some common traits that we see over and over again of effective FDA compliance programs. The most important of these traits being internal business processes that focus on finding and fixing internal issues that can affect compliance. FDA strongly prefers that firms find and rectify their own problems, rather than wait for the agency inspector to show up. For this very reason, it is FDA enforcement policy that the results of any internal audits are not required to be shared with agency inspectors visiting your facility. FDA understands that if their inspectors use your internal audit reports as a roadmap to preparing their inspection report, the number of audits firms will voluntarily perform will quickly drop to zero.

The evolution of complete compliance

However, FDA can see the corrective actions firms implement when they perform audits. As FDA performs their site inspection function and see the improvements firms have implemented their thinking on what constitutes complete compliance in our industry evolves as well. At first, these evolutionary changes in practices are written up and circulated among FDA inspectors as compliance notes. Eventually they find their way into compliance guidance or even the regulations. In this way the compliance requirements we are subject to continually evolve based on the actions of the manufacturers, and without being actively driven by FDA.

The spread of evolutionary practices in our industry, and how it can affect the compliance activities of medical producers is unique to our industry, in that it is much quicker. No other segment of the pharmaceutical industry is as

highly standardized as the gases industry. The highly competitive and cost conscious nature of our industry virtually guarantees that most of the over 3,000 registered medical gas manufacturers are using virtually the same equipment, components, analytical equipment, procedures, and manufacturing methods. Unlike more traditional pharmaceutical manufacturing firms, where an improvement made by one company may, or may not be applicable to another company, in the gases industry an improvement made by one company is almost guaranteed to be applicable to everyone else in the industry. This is why a ripple at one end of the medical gas compliance pond is usually quickly felt by the entire industry. Keeping abreast of compliance trends and

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changes in practices in the gases industry is an important element to running an effective compliance program today.

Compliance trends in bulk gas systems at healthcare facilities

One of the bigger industry driven compliance trends in medical gases to come along in the last decade involves bulk gas systems installed at healthcare facilities. Starting in the late 90's, and beginning with the major gas companies, firms began to upgrade their procedures and practices governing how these systems were installed and maintained.

A few years later system validation of hospital bulk systems, along with more thorough documentation of the installation process, and the involvement of the firms Quality Control Unit in reviewing and approving these systems, became the accepted industry practice. The evolution in requirements did not stop there, as in the last two years an evolution in the training and certification requirements for individuals who install and maintain these units has begun to move through the industry. Since the introduction of the *ASSE 6015* standard, firms have begun certifying their technicians to this standard, and others are attending training sessions to learn more about this initiative. Inside of ten years the accepted cGMP requirements to be involved in installing and

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maintaining bulk systems at healthcare facilities have changed dramatically, and have almost all been driven forward by companies in our industry changing their practices, not through an intervention by FDA.

A second compliance trend in the gases industry largely being driven forward by changing industry practice is the validation of high pressure cylinder fill systems. FDA originally stimulated this activity in the mid 90's when they decreed that all portable roll-up manifolds, connected to a permanently installed fill manifold needed to be validated. This industry practice subsequently expanded, as firms began validating their new high pressure fill systems. Predominately the systems being validated at this time were being used to fill the latest in technology of the day, the valve and integrated pressure regulator (VIPR) units, originally called Grab 'n Go units. Even though there was no clear cut FDA edict to perform validation, the filling processes of these units were different enough that many companies felt validation was an appropriate activity to qualify these new systems, and forestall any potential FDA concerns. As companies in our industry also began to understand the economic and operational benefits to be gained from validating their systems, this practice started to take on a momentum of its own.

Today, validation of high pressure manual filling systems is well on its way to becoming an accepted and commonly adopted practice. By our rough estimate, something approaching half of all manual fill systems in use today have undergone some degree of a validation exercise. Further evidence that this compliance requirement has achieved the status as an accepted industry practice is that CGA will soon be releasing a publication on the requirements for validating high pressure cylinder manual fill systems. It should therefore; come as no surprise to anyone in the medical gas industry filling high pressure cylinders that an FDA inspector could show up at your site sometime in the near future and expect to see your system's validation study.

The impact of industry practices on electronic data technology

A third area we see where industry practices having an impact on compliance requirements is electronic data technology. With the advent of highly cost effective hand held and computer based record keeping technologies coupled with the ever present need to improve operational efficiencies in cylinder filling, electronic systems and devices are making their way into all areas of medical gas manufacturing. This technological evolution to a paperless system also opens the door to new set of compliance requirements manufacturers must now face. This is an example where evolving business practices and the adoption of new technology end up driving changes in compliance activities. Early adopters of new technology usually shoulder the largest burden in developing new compliance practices. Subsequent adopters are able to start higher on the learning curve and build on what the earlier adopters have built. As the technology begins to mature often the manufacturers of the new technology will be in a position to offer customers compliance tools, or at least point them to consultants such as B&R, who are experienced in helping firms adopt new technology into their compliance programs.

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Good news for today's adopters

The good news is that electronic systems for medical gas applications, along with the attendant compliance requirements, have already been pioneered by a number of companies, and today's adopters will not be facing the regulatory challenges of the earlier adopters. We are also finding that many manufacturers now understand that if they are able to offer their customers assistance on the compliance aspects, it can facilitate the sale process. If you are currently contemplating adopting a new or upgraded data capture or recordkeeping system you should not sign the check until you explore what the system manufacturer has to offer you in the way of compliance material, tools, assistance, and advice. As this new technology spreads through the industry FDA inspectors will be observing how the industry has integrated this new technology and adapted their compliance practices. As this happens the cycle of regulation and evolution of industry practices will start once again.

In today's tough economy smaller medical gas firms are well advised to pick suppliers of technology and equipment who have the internal expertise, or are partnered with compliance experts like B&R, who can assist them both in the adoption of new technologies, as well as the supporting compliance practices through every phase of the project. If you have questions about the adoption of new technologies, or medical gases in general, give us a call. SGR

Ron Ball

For more information on regulations that affect medical gas producers and end-users contact:
Ron Ball at B&R Compliance Associates LLC
+1 (317) 297-8518; e-mail: **ron.ball@brcompliance.com**; go to: **www.brcopliance.com**