



## Survey Results: USP <797> Compliance

**W**ith the updated USP <797> requirements becoming official on June 1, 2008, compliance will no longer be up for debate. Given the turmoil surrounding <797> over the past four years, the upcoming deadline prompted our desire to learn how directors of pharmacy currently view compliance, what changes they are making to achieve compliance, and how they rate the solutions they have been using. Hence, we are very pleased to bring you the results of our first annual survey on the “State of Pharmacy Compounding.”

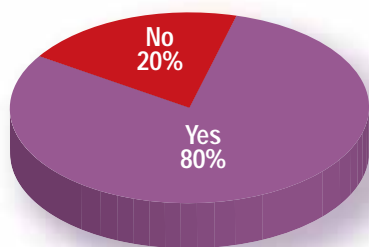
### Survey Methods

In the first quarter of 2008, *Pharmacy Purchasing & Products (PP&P)* polled a random, nationwide sampling of health-system pharmacists. We asked about compliance with <797>, regulatory experiences, compounding environments, satisfaction with current solutions, and plans for future compliance. Responses were solicited via mail and e-mail, and a total of 225 were received, yielding a confidence interval of 6.39% (95% +/- 6.39) based on the total population of pharmacy directors nationwide.

We intentionally survey a random sampling of pharmacists – not just readers of *PP&P* – to capture data that reflects trends across the entirety of health-system pharmacy practice. Therefore, we were quite

pleased to see that 80% of respondents use *PP&P* as a resource for <797> information (See Figure 1).

**Figure 1. PP&P as a Resource for <797> Questions**



### Widespread Changes, Need, and Acceptance

Our survey results demonstrate that health-system pharmacy has entered an era of change. Cleanrooms are now used in the majority of facilities, and growth is projected for future installations. An increase is also predicted in the outsourcing of CSPs and the implementation of environmental monitoring plans.

We are reminded of the need for USP <797>, as 31% of respondents report that a patient incident involving a compounding error has occurred at their institution in the past five years. Regulatory interest in compliance is also keen, with both The Joint Commission and state boards of pharmacy asking questions relative to <797> compliance during surveys and inspections.

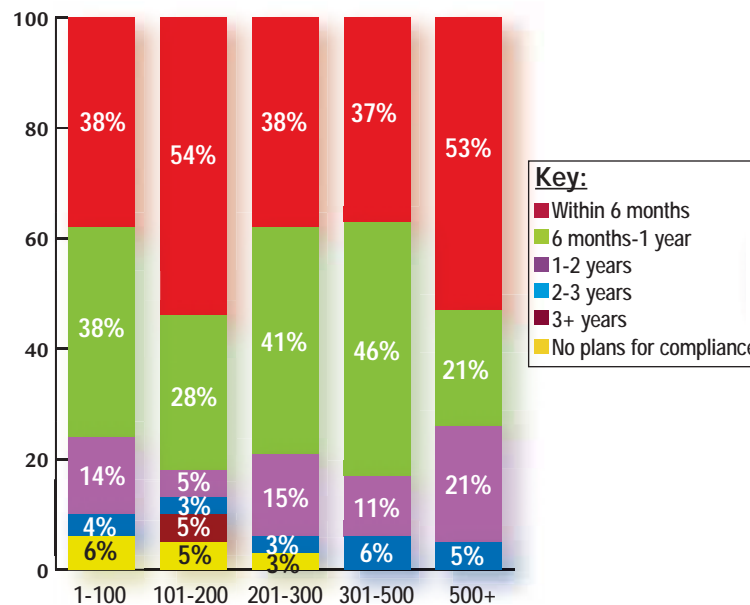
There is broad acceptance of <797> by health-system pharmacy as indicated by respondents' reported levels of compliance and projected timeframes to complete compliance (see page one). While the few facilities

with no plans for compliance are smaller hospitals, projections of complete compliance within one year hold relatively steady across all bed sizes. (See Figure 2.)

### Budgeting

With respect to pharmacy budgets, there is both good news and bad: Getting budget approval for pharmacy renovations remains a challenge; however, the majority of hospitals report renovating their pharmacies for \$250,000 or less.

**Figure 2. Projected Compliance by Facility Size (in number of beds)**



### Opportunities for Improvement

Our results also indicate that many opportunities exist for significant improvement. There are challenges with the preparation of medications on the patient floors. While many institutions report that nursing compounds/prepares medications on the floor, most have not received proper training by pharmacy, and very few of these nurses are required to verify their aseptic training. Environmental monitoring is another area where improvements can be instituted: Pharmacists report some dissatisfaction with current monitoring processes, the number of facilities conducting challenge testing of their monitoring equipment is relatively low, and few pharmacies have their own incubators. When it comes to training for compounding personnel – an area USP strongly emphasizes – improvements are needed in the regularity in which training is provided. Furthermore, most pharmacists have yet to take advantage of working

with their risk management department to get the resources necessary to comply with <797>.

### Product Satisfaction

As you move toward full compliance, feel confident that there are many excellent product choices to help you achieve your goal. Pharmacy directors report markedly high satisfaction with:

- Compounding aseptic isolators
- Cleaning products
- Laminar airflow workbenches
- Outsourcing services

### Conclusion

Lots of change is underway in compounding environments, processes, and training. While you prepare for compliance, use *PP&P* as a resource to prioritize your budget needs, develop best practices, and measure your progress against your peers. When researching HVAC solutions, developing cleaning SOPs, and investigating outsourcing solutions, the daily minutiae can obscure the ultimate goal. Remember that the results of your committed effort to achieving compliance are eliminating the risk of patient harm from contaminated CSPs and protecting your compounding staff from potentially dangerous exposures. ■

### Acknowledgements:

*PP&P* would like to extend our grateful appreciation to the pharmacy leaders who responded to this survey. Their thoughtful and thorough responses bring great value to this benchmarking tool.

In addition, *PP&P* would like to thank Eric Kastango, Bill Churchill, Stephen Eckel, and Carlo Lupano for their considerable insight and expert advice in creating the survey.



## in contamination control for USP <797> compliance

USP <797> describes the cleaning practice for compounding sterile preparations. ITW Texwipe® provides the cleaning products for compliance:

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- Sterile 70% IPA
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