MDR Exceptions and Variances

21 CFR §803.19 includes methods to request exemptions, variances, or alternative forms of adverse event reporting under the MDR regulation. This article discusses some types of requests.

Remedial Action Exemption (RAE)
The guidance document *Medical Device Reporting – Remedial Action Exemption; Guidance for Industry and FDA* (UCM071377) describes the process for the exemption.

The MDR regulation requires manufacturers to report adverse events for products undergoing remedial action. FDA intends to grant an exception to manufacturers that provide information showing additional reports about a device subject to a remedial action won't provide any significant new data.

The following conditions apply:

- Submit the Remedial Action Exemption (RAE) to FDA-CDRH with (or after) a 5-day or 30-day initial report
- Provide information about the device, the remedial action, *etc*.
- Notify the District Office
- Conduct a complete complaint investigation under §820.198

Alternative Summary Reporting (ASR)
The guidance document *Medical Device Reporting – Alternative Summary Reporting (ASR) Program* (UCM072102) provides an exemption from the individual event reporting requirements of sections §803.50 and §803.52 for specific devices an adverse event types. Instead, describe the events in a line item format reported to FDA each quarter. The ASR reports must contain the data elements listed in Attachment A of the guidance document.

Specification Developer and Contract Manufacturer
Since both parties are manufacturers, they must both submit MDRs for the same event. However, if the parties agree that only one should submit the MDR, they can ask for a variance. FDA prefers that both parties submit the request at the same time.

Time to Submit
The MDR regulation specifies the time to submit each type of report, but the regulation has provision for a variance request.

As an example, a January 3, 2012 Warning Letter to Thoratec Corporation says, "Under the authority of 21 CFR §803.19(e), your firm was granted an exemption from the 30 calendar day reporting timeframe required by 21 CFR §803.50(a)(1) for events that your firm receives from the INTERMACS Registry. However, your firm did not submit an MDR to FDA within the 90 calendar day timeframe for the following [complaint]".