

# Case study example: Strategic regulatory services

## Anesthesia gas recycling and reuse project

<b>Client</b>	<ul style="list-style-type: none"><li>• A North American pharmaceutical manufacturer with novel anesthesia technology being developed for North American markets</li></ul>
<b>Situation / Challenge</b>	<ul style="list-style-type: none"><li>• Manufacturer developed safe technologies not in previous practice for purification and reuse of anesthesia gases</li><li>• The global regulatory agency was not supportive of the technology</li><li>• Refused application based on a specific but non-viable concern about potential impurities</li><li>• File was eventually taken to appeal</li></ul>
<b>Our Solutions</b>	<ul style="list-style-type: none"><li>• <u>Regulatory Consulting</u>: OptumInsight recommended use of an external, expert review panel for impartial technological expertise; panel unanimously overturned decision of agency</li><li>• <u>Regulatory Technical Services</u>: The file is now continuing through the regulatory approval process</li></ul>
<b>Results</b>	<ul style="list-style-type: none"><li>• OptumInsight provided effective, timely consulting that resolved the hold placed on the technology by the regulatory agency</li><li>• OptumInsight enabled product to continue through the approval process and to be reviewed with appropriate technological assessment of the platform</li></ul>