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Allegheny Performance Plastics Advances Toward ISO 13485 Certification for Medical Manufacturing

Leetsdale, Pennsylvania, June 17, 2025

Allegheny Performance Plastics, a global leader in high-performance thermoplastic components, is proud to announce significant progress in its pursuit of ISO 13485 certification—an internationally recognized standard for quality management systems in the medical device industry.

The company has successfully completed both lead auditor training and a comprehensive gap analysis, marking major milestones in its path to certification. These steps are part of Allegheny's strategic initiative to expand its footprint in the medical manufacturing sector.

Lead auditor training equips key personnel with the ability to independently assess the company's internal quality systems for compliance, identification of process risks and continuous improvement.

Gap analysis is another critical step that identifies areas of improvement needed to meet ISO 13485 standards. By conducting a full review of current systems and comparing them to certification requirements, Allegheny is proactively closing gaps and reinforcing its medical manufacturing infrastructure.

"As we progress on current expansion plans, achieving ISO 13485 is key to our business strategy. The addition of this certification will bolster our overall QMS and align us with our customer requirements while enabling us to meet the demands of this growing industry segment," said Robert Stutzman, CEO of Allegheny Performance Plastics.

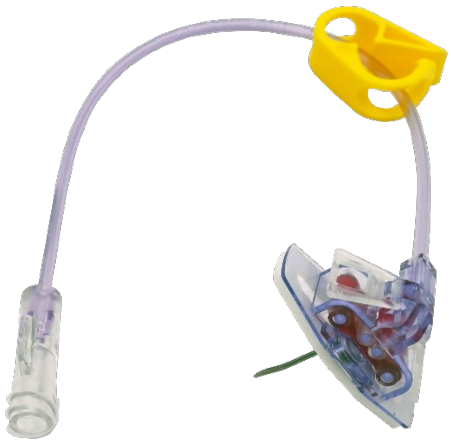
Allegheny Performance Plastics expects to achieve ISO 13485 certification by the end of the year, strengthening its position as a trusted injection molder for complex medical components.

For more information about Allegheny's capabilities and certifications, visit www.alleghenyperformanceplastics.com.

Read more about Allegheny's work in the Healthcare sector on their website here: https://alleghenyperformanceplastics.com/industries/healthcare/. Review a case studies

highlighted their work in the medical field: [Reshoring an Oncology Infusion Needle Assembly - Allegheny Performance Plastics®](#).

About us: Allegheny Performance Plastics® is redefining what an injection molding partner is for high-tech, high-performance brands. They can deliver your superior new product using a unique, highly collaborative process. Allegheny molds parts in the aerospace, space, defense, medical and e-mobility industries, as well as many others. With capabilities that include in-house prototype manufacturing, tool repair and machining, as well as injection-molding high-temperature polymers such as PPS, PEI, PAI, PBI and PEEK, they are innovating a new, customer-centric process that delivers the right solution for customers. Solve your engineering or manufacturing problem with their help, visit www.alleghenyperformanceplastics.com.



Huber Infusion Set, view the case study here: https://alleghenyperformanceplastics.com/case-studies/reshoring-an-oncology-infusion-needle-assembly/