lborton@gradientcorp.com

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(she/her)

Areas of Expertise

- Medical Device Regulations
- Risk Assessment & Biocompatibility
- Pharmaceutical Non-clinical Safety Assessment
- Product Safety

Services

- Biocompatibility Support
- Toxicological Risk Assessment (TRA)
- Biological Evaluation Plans
- Medical Product Liability
- Extractable & Leachables
- Non-clinical Safety Assessment Support
- Impurity Assessments
- Permissible Daily Exposures

Education

- M.P.H., Regulatory Toxicology and Risk Assessment, University of Minnesota
- B.S., Biomedical Engineering, *magna cum laude,* Michigan Technological University

Lindsey K. Borton, M.P.H.

Principal

Ms. Borton is a toxicologist and engineer with 10+ years of industry experience in medical device biological safety and risk assessment. At Gradient, Ms. Borton develops strategies for the biological safety assessment of medical devices in support of European, US FDA, and other worldwide medical device regulations. She also performs toxicological risk assessments of extractable and leachable compounds for human health risk assessment.

Selected Projects

Benefit-Risk Justification: Provided compliance documentation and support for the European Union Medical Device Regulation (EU MDR), Regulation (EC) No 2017/745, Annex I, General Safety and Performance Requirements (GSPR) 10, including authoring benefit-risk justifications for the presence of a carcinogenic/mutagenic substance.

Compliance Strategy Development: Met with EU Notified Body (BSI) in support of Notified Body conversion and Medical Device Directive (MDD) to MDR compliance. Developed a strategy to achieve EU MDR compliance to ISO 10993 and oversaw execution of the strategy for 12+ product lines, ranging from long-term implants to transient contact medical devices, and intact skin contact medical devices to highly invasive medical devices.

Biological Evaluations for Drug/Fluid Administration Sets: Developed and conducted biological safety evaluation strategies for two unique drug/fluid administration set families (510k/CE approved). Authored biological safety evaluation plans and reports inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Biological Evaluations for Pain Management Kits: Developed and conducted biological safety evaluation strategies for neuraxial pain management kits (510k/CE approved). Authored biological safety evaluation plans and reports inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations to address drug compatibility, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Biological Evaluations for Tracheostomy Tubes: Led biological safety evaluation strategies for breathing gas pathway tracheostomy tubes (CE approved). Reviewed biological safety evaluation plans and reports inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Biological Evaluations for Implants: Developed and conducted biological safety evaluations for three metal implants (pre-market approval [PMA] and 510k/CE approved) and one tissue implant (510k/CE approved) and their related delivery system accessories (510k/CE approved). Authored biological safety evaluations inclusive of *in vivo* and *in vitro* biocompatibility results, chemical characterization evaluations, toxicological risk assessments, material and manufacturing analyses, and justifications for non-testing.

Animal Safety and Efficacy Assessment: Collaborated with clinical team to conduct and utilize large animal safety and efficacy studies (canine, swine) to meet the ISO 10993 endpoints of implantation and hemocompatibility to conserve animals while reducing cost.

Selected Publications

Cabrera, JA; **Borton, L.** 2020. "Quantification of safe aluminium levels released into infusion solutions by the Level 1 Fast Flow Fluid Warmer: A reply." *Anaesthesia* 75:1253-1254.

Cabrera, JA; **Borton, L;** Barrett, G. 2020. "Quantified aluminium levels released into blood and fluids using the Level 1 Fast Flow Fluid Warmer." *Anaesthesia* 75:271-281.

Borton, L; Coleman, K. 2018. "Material-mediated pyrogens in medical devices: Applicability of the *in vitro* monocyte activation test." *ALTEX* 35(4):453-463.