Based on the context and safety case pattern predicates provided for the Generic Patient-Controlled Analgesia (GPCA) system, the instantiated safety case tree would look like this. We assume placeholders for goals, strategies, solutions, and contexts have been replaced with specific system-related or concrete information.

### GPCA Safety Case Tree

- \*\*G1: Operational Safety is Verified in GPCA System\*\*

- \*\*S1: Argument over the satisfaction of all specs over GPCA system\*\* (Undeveloped)

- \*\*G2: All Operational Hazards are Mitigated\*\*

- \*\*S3: Argument Over Operational Hazards\*\*

- \*\*G3: Overinfusion is Mitigated\*\*

- \*\*S4: Argument over the Applied Scenarios of Overinfusion\*\*

- \*\*G4: Overinfusion is Mitigated Under Scenario "Bolus volume/concentration too high"\*\*

- \*\*S5: Argument over all specs related to "Bolus volume/concentration too high"\*\*

- \*\*G5: Flow rate sensor is appropriate for "Bolus volume/concentration too high"\*\*

- \*\*S6: Argument the appropriateness of 'Flow rate sensor' over properties\*\*

- \*\*G6: Property 'Flow rate less than 90% of the programmed rate setting' is appropriate for 'Flow rate sensor'\*\*

- \*\*S7: Argument Over the Source of the Property Definition\*\*

- \*\*G7: Source 'FDA standard' is appropriate and trustworthy\*\*

- \*\*Sn1: FDA approval documentation\*\*

- \*\*G8: Property definition 'Flow rate less than 90% of the programmed rate' is sufficient\*\*

- \*\*Sn2: Scientific studies confirming accuracy of this threshold\*\*

- \*\*S2: Argument Over Reliability in All Suitable Levels of GPCA System\*\* (Undeveloped)

### Contexts and Supporting Information

- \*\*C1: All Specs Given by GPCA Specs Documentation\*\*

- Linked to: \*\*S1\*\*

- \*\*C2: Operational Hazards Given by GPCA Hazard Analysis\*\*

- Linked to: \*\*S3\*\*

- \*\*C3: All Related Scenarios Given by GPCA Scenario Analysis\*\*

- Linked to: \*\*S4\*\*

- \*\*C4: All Related Specs Given by GPCA Scenario-Specific Documentation\*\*

- Linked to: \*\*S5\*\*

- \*\*C5: Properties Given by GPCA System Specifications\*\*

- Linked to: \*\*S6\*\*

- \*\*C6: Source is Given by GPCA Regulatory Compliance Documentation\*\*

- Linked to: \*\*S7\*\*

This tree structure shows how each goal and strategy is supported by lower-level goals, contextual information, and evidential solutions, creating a traceable argumentation path that ensures all aspects of GPCA's operational safety are addressed.