### Instantiated Assurance Case for GPCA System

- Goal (G1, Operational safety is verified in Generic Patient-Controlled Analgesia system)

- Strategy (S1, Argument over the satisfaction of all specs over Generic Patient-Controlled Analgesia system) - UNDEVELOPED

- Context (C1, All specs are given by FDA standards, Expert opinions and Previous Knowledge)

- Goal (G2, All operational hazards are mitigated)

- Strategy (S2, Argument over reliability in all suitable levels of Generic Patient-Controlled Analgesia system) - UNDEVELOPED

- Strategy (S3, Argument over operational hazards)

- Context (C2, Operational hazards are given by potential causes such as flow rate mismatch, programmed rate issues, dose limit exceeded)

- Goal (G3, Overinfusion is mitigated)

- Strategy (S4, Argument over the applied scenarios of Overinfusion)

- Context (C3, All related scenarios are given by possible operational contexts)

- Goal (G4, Overinfusion is mitigated under likely scenarios)

- Strategy (S5, Argument over all specs related to likely scenarios)

- Context (C4, All related specs are given by safety requirements like SR1.1, SR1.2, SR1.4)

- Goal (G5, Safety requirements are appropriate for likely scenarios)

- Strategy (S6, Argument the appropriateness of safety requirements over properties)

- Context (C5, Properties are given by specs like Flow rate sensor equipped, Trigger period is 15 minutes)

- Goal (G6, Flow rate settings are appropriate for safety requirements)

- Strategy (S7, Argument over the source of the property definition)

- Context (C6, Source is given by standards like FDA)

- Goal (G7, Source FDA standard is appropriate and trustworthy)

- Solution (Sn1, Source verification documentation)

- Goal (G8, Property definition of flow rate settings is sufficient)

- Solution (Sn2, Detailed specifications and tests reports)

This safety case structure represents a structured argumentation using the GSN for ensuring the operational safety of the GPCA system by mitigating identified hazards like overinfusion and underinfusion through the instantiation of predefined patterns. Each element respects the hierarchical structure, supported by each other and grounded on context or evidence as required.