

**Praktik Kerja di PT. Forsta Kalmedic Global Periode 1 Maret - 28 April 2023, Analisis Risiko Proses Needle Attaching Menggunakan Alat Needle Attach dan Pull Test di PT. Forsta Kalmedic Global =
Professional Internship at PT. Forsta Kalmedic Global Period 1st March until 28th April 2023, Risk Analysis of Needle Attaching Process Using Needle Attach and Pull Test Instruments at PT. Forsta Kalmedic Global**

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Abstrak

Alat kesehatan merupakan salah satu komponen penting disamping tenaga dan obat dalam sarana pelayanan kesehatan. Pengembangan industri farmasi dan alat kesehatan diselenggarakan dengan meningkatkan kapabilitas dan kapasitas industri farmasi dan alat kesehatan dalam negeri dengan prioritas obat dan alat kesehatan nasional, termasuk untuk ekspor. PT. Forsta Kalmedic Global merupakan salah satu industri yang bergerak di bidang manufaktur alat kesehatan dan diagnostic. Pentingnya pelaksanaan kegiatan operasional dan pemeliharaan mesin produksi PT. Forsta Kalmedic Global dengan melakukan penilaian resiko mutu. Manajemen risiko mutu adalah suatu proses sistematis untuk melakukan penilaian, pengendalian, komunikasi dan pengkajian risiko terhadap mutu obat. Industri farmasi dapat menilai dan mengelola risiko dengan menggunakan perangkat manajemen risiko dan/atau prosedur internal. Salah satu contoh perangkat dalam penilaian dan pengelolaan risiko ialah Failure mode and effects analysis (FMEA). Berdasarkan hasil penggalan informasi, didapatkan berbagai macam kelompok aktivitas needle attaching dengan berbagai tingkatan potensi risiko.

.....Medical devices are one of the important components besides energy and drugs in health service facilities. The development of the pharmaceutical and medical device industry is carried out by increasing the capability and capacity of the domestic pharmaceutical and medical device industry with national drug and medical device priorities, including for export. PT. Forsta Kalmedic Global is one of the industries engaged in manufacturing medical devices and diagnostics. The importance of implementing operational activities and maintaining production machines of PT. Forsta Kalmedic Global by conducting a quality risk assessment. Quality risk management is a systematic process for assessing, controlling, communicating and assessing risks to drug quality. The pharmaceutical industry can assess and manage risk using risk management tools and/or internal procedures. One example of a tool in risk assessment and management is Failure mode and effects analysis (FMEA). Based on the results of extracting information, various groups of needle attaching activities with various levels of potential risk were obtained.