# Penyusunan dan pengembangan protokol kualifikasi kinerja mesin autoclave kapasitas 500 liter di PT. Forsta Kalmedic Global = Preparation and development of performance qualification protocol for an autoclave within 500 liter of capacity at PT Forsta Kalmedic Global

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Abstrak

PT. Forsta Kalmedic Global merupakan industri yang bergerak dalam bidang manufaktur alat kesehatan. Salah satu produk yang sudah mulai dipasarkan dan masih akan terus dikembangkan adalah media kultur broth. Dalam proses produksinya, sterilitas produk merupakan salah satu titik kritis keberhasilan produk dalam menjamin mutu produknya dengan sterilisasi terminal untuk proses produksi media broth adalah autoclave. Sebelum penggunaan autoclave dalam skala produksi, setiap alat baru di industri harus melewati beberapa rangkaian kualifikasi dan validasi peralatan untuk memastikan kualitas, keamanan, hingga efikasi selama siklus hidup produk. Kegiatan kualifikasi sendiri terdiri dari beberapa rangkaian yaitu kualifikasi desain, kualifikasi instalasi, kualifikasi operasional, dan kualifikasi kinerja (WHO, 2019). Berdasarkan ISO 17665-1:2006 (E), kualifikasi kinerja harus membuktikan bahwa produk yang disterilisasi terpapar agen sterilisasi dengan baik saat produksi rutin. Oleh karena itu, tujuan dari pelaksanaan tugas khusus ini adalah memahami tahapan pembuatan penyusunan protokol kualifikasi kinerja autoclave dan memperoleh protokol kualifikasi kinerja autoclave yang dijadikan sebagai pedoman kegiatan pelaksanaan kualifikasi. Kegiatan ini dilaksanakan melalui studi literatur mengenai kualifikasi kinerja mesin autoclave. Setelah seluruh data dan sumber terkumpul, dimulailah proses pembuatan dan penyusunan dokumen protokol kualifikasi kinerja autoclave menggunakan software Microsoft Word. Hasil dari kegiatan kualifikasi instalasi dan operasional autoclave telah selesai dilaksanakan dan perlu dilanjutkan untuk pelaksanaan kualifikasi kinerja sedangkan protokol kualifikasi kinerja autoclave kapasitas 500 liter telah berhasil disusun yang terdiri dari tiga jenis pengujian yaitu Heat Distribution Study (Loaded Chamber), Heat Penetration Study (Loaded Chamber), dan Biological Challenge Test.

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PT. Forsta Kalmedic Global is an industry engaged in the manufacturing of medical devices. One product that has started to be marketed and will continue to be developed is broth culture media. In the production process, product sterility is one of the critical points of product success in guaranteeing product quality by means of terminal sterilization for the production process of broth media, namely the autoclave. Before using the autoclave on a production scale, every new tool in the industry must go through several series of equipment qualifications and validations to ensure quality, safety, and efficacy throughout the product life cycle. The qualification activities themselves consist of several series, namely design qualifications, installation qualifications, operational qualifications, and performance qualifications (WHO, 2019). According to ISO 17665-1:2006 (E), the performance qualification must prove that the product being sterilized is properly exposed to the sterilizing agent during routine production. Therefore, the purpose of carrying out this special task is to understand the stages of making the preparation of an autoclave performance qualification protocol and obtain an autoclave performance qualification protocol which is used as a guideline for conducting qualification activities. This activity is carried out through a literature study

regarding the performance qualifications of autoclave machines. After all the data and sources have been collected, the process of creating and compiling the autoclave performance qualification protocol document begins using Microsoft Word software. The results of the autoclave installation and operational qualification activities have been completed and need to be continued for the implementation of the performance qualification while the 500 liter capacity autoclave performance qualification protocol has been successfully compiled which consists of three types of tests namely Heat Distribution Study (Loaded Chamber), Heat Penetration Study (Loaded Chamber), and the Biological Challenge Test.