

Outsourcing manufacturing : the example of a sustainable partnership

A wide number of firms regularly call on subcontractors. However, this relationship can bring its share of uncertainties, especially in terms of responsibility. During “La Rentrée du DM 2022”, both firms MID and Sterne shared some key points about their long lived 15 years partnership.

Located in Dardilly (69), MID is a regulatory manufacturer specialized in the design, manufacture and commercialization of silicone medical devices for use in bariatric and wound surgery. Since 2009, the firm has collaborated closely with Sterne, located in Cavillon (84). The latter is dedicated to the development and industrialization of assemblies made of silicone elastomer materials. A great example of a long lived partnership that relies on carefully elaborated basis.

Establishing contractual documents

Subcontracting has long been neglected in favor of strict respect for obligations. With the entry into force of the European Medical Device Regulation (MDR 2017/745), it is clearly defined that product responsibility lies with the manufacturer. Therefore, it is in its interest to work with reliable subcontractors and to know them well. The contracts, agreements, norms matter greatly today as they allow to define each party's roles, to precise responsibilities and to optimize resources.

While Sterne has centralized its organization around its Quality Management System, a guarantee of professionalism, its partnership relationship with MID is nonetheless defined in an industrial contract. And both parties don't stop there. In addition, supplier specifications are systematically drawn up for each product manufactured. They specify the product description, the service details, and the manufacturing method (purchasing, labeling, origin, conditioning, designation, controls, employees qualifications, certifications,...). These documents are not rigid as they can evolve all along the product life.

Maintaining the link

A good project management requires regular exchanges, by emails, phone calls or in person. It matters for the manufacturer to carry out audits of its subcontractors to ensure they master the processes entrusted to them. Also, in addition of an annual audit, MID and Sterne organize at least one production meeting per year. The latest allows them to verify the operations advancement state following the decisions taken during the previous year, and the key decisions to be implemented next year.

Carrying a joint approval

If, depending on the validation steps, responsibilities are not the same, it matters to keep in mind the processes validation must be joint. Indeed, one of the two partners can, for example, hold the knowledge and expertise of processes, and the other one the knowledge of the certification requirements. Thus, everyone contributes to the process of validation. Any need for changes requires the prior transmission of information to the other party, and all decisions must be taken jointly, taking into account the financial impact for both parties.

Improving teams' involvement through workshops

For Sterne, it is essential that all of its collaborators involved in a project are aware of its meaning. In order to do so, the firm organized a workshop for its teams, concordant with MID. The surgeon using the device was present to explain the importance of each step of manufacturing and the risks regarding non-conformities for the patient. A question box was made available to the surgeon beforehand so he could answer the questions of everyone. Exchanges were thus built, allowing to enhance teams' work.