

<p>The Vacu-Braze Inc Quality Management System is certified in AS9100D and ISO 13485:2016. Our external providers supplying products and services are an integral part of our strategic plan for continuous improvement and growth. The mutual obligations with our external providers are as follows:</p>
<p>VBI will provide the specifications, drawings, and Work Instructions for products and services according to internal, customer, statutory, and regulatory requirements.</p>
<p>VBI shall define the requirements for approval and release of processes, products, and services</p>
<p>(a) The requirements of our External Providers are defined in VBI Procedure QMP-840. All VBI purchasing documents shall contain a clear description of the products and services required and shall include the following Terms and Conditions.</p>
<p>(b) Our external providers are requested to notify Vacu-Braze immediately of known discrepancies in the specifications provided.</p>
<p>(c) VBI Terms and Conditions for External Providers include personnel competence and qualification for conformance with the requirements of the VBI Purchase Order.</p>
<p>(d) VBI requires the External Provider initiate communication with VBI with respect to issues of specifications, processes, inspection results, non-conformances, delivery, and certification.</p>
<p>(e) The External Provider shall recognize that Approved Supplier status is based on VBI evaluation of quality conformance and delivery performance in subsequent approval processes.</p>
<p>(f) The External Provider shall grant VBI the right for to perform validation activity on the premises as is reasonable to the product requirements and production processing.</p>
<p>(g) The External Provider shall recognize the potential for VBI to request design and development control in unique process or product discussions.</p>
<p>(h) The External Provider shall recognize the right for VBI to define and require critical items or key characteristics measurement as well as the right to define inspection and verification processes as well as the potential for statistical techniques in product measurement for acceptance.</p>
<p>VBI shall communicate to the External Provider the following Quality Management System requirements</p>

(i) The External Provider shall implement and maintain a Quality Management System
(j) The External Provider shall use only customer-designated or approved external providers
(k) The External Provider shall notify VBI of nonconforming processes, products or services
(l) The External Provider shall obtain VBI approval for disposition of non-conforming processes, products or services
(m) The External Provider shall prevent the use of counterfeit parts or materials
(n) The External Provider shall (a) notify VBI of changes to processes, products, or services, (b) shall notify VBI of changes including changes by external providers, and (c) shall obtain VBI approval for changes
(n) The External Provider shall flow down to external providers applicable requirements
(o) The External Provider shall provide test specimens for inspection and verification
(p) The External Provider shall retain documented information in accordance with the defined specifications in the VBI Purchase Order. In cases where the retention time is not defined in the Purchase Order, records shall be retained in accordance with ISO 13485:2016 and AS9100D and the relevant regulatory requirements.
The External Provider shall provide VBI the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information,
The External Provider shall ensure that staff members are aware of their contribution to product or service conformity, their contribution to product safety, and the importance of ethical behavior.
Vacu-Braze Inc requires the completion of the Supplier Quality Management System Survey and requests the right to conduct an on-site audit annually at a scheduled time agreeable with our supplier. In lieu of the QMS Survey, Vacu-Braze Inc shall accept the supplier's QMS Certification, which shall not remove the right for an on-site audit.
Vacu-Braze Inc shall evaluate and approve our suppliers annually based on the supplier's Quality Management System Certification and measured by the provision of products and services conforming to all requirements, including delivery date.