A Corporate Profile

Who we are.....
Overview

Tektran has been in business since 1991, when a group of senior level electronic engineers with experience in RF electromedical power systems got together to form a product realization service. Tektran is classified as a third party design contractor according to the FDA.

The company’s mission, since its inception is to address the growing list of RF applications, mainly for minimally invasive surgery in all areas of medical specialties. Our clients provide us with their product specifications and using protocols based on the FDA(c)GMP QSR (Quality System Regulations) and ISO 13485 quality management system standards we make that product a reality. For the last 22 years we have been focused on product development services related to electrosurgery, ablation, and coblation power sources to power our client’s cutting edge devices.

Tektran, from its inception embraced the “hub and spoke” concept in order to keep its operating burden to a minimum which is typically reflected in our competitive quotes. To that end, whether to address protocol validation runs or regular production, Tektran partners with one of the most advanced EMS (Electronic Manufacturing Service) firms in the Pacific NW, just minutes away. Refer to our EMS brochure under “Production” using our website menu.

Tektran engages both “turnkey” and “collaborative” assignments. Our “turnkey” assignments include everything from Industrial Design and FRD (Functional Requirements Documents) to production. Although, in most cases clients are handed off production after we complete a protocol run of pre-production models to validate the DMR (Device Master Records) or build documents for transfer to production.

We also contract to perform collaborative project assignments with either the client directly or with other major outsource contractors. It is not uncommon for us to engage projects with three or more outsource contractors working cooperatively for a client firm - each providing that client with engineering services based on their specific skill sets or capabilities. For example, although Tektran has the skill sets in place to complete turnkey projects, its main skill sets are in the area of RF/HF power systems - from the AC Mains to the output circuit.

Since EMC (Electromagnetic Compatibility) is of major concern to our clients and our partnering contractors, they often look to Tektran to draft the entire systems schema, including the I/O interface for the digital to analog circuits and pre-design considerations for EMI/RFI issues. As part of that specialty skill set we also have many years experience designing the many types of custom RF/HF transformers and other electromagnetic components that are always a major part of any RF electromedical power source. Tektran maintains an inventory of cores, tapes, and special wire.

When we engage collaborative projects the division in labor or work products is detailed in our PDP (Product Development Plan) for all parts of the project.

Product & Project Definition

The first thing we do when a prospective client approaches us is enter into a Reciprocating Non-Disclosure Agreement (R-NDA). This protects the client and us. Neither Tektran nor our EMS sell products under their own label - both companies are in business for one reason - to provide service our clients.

However, over the years Tektran has designed and developed on its own a library of functional circuits which greatly reduces the development turn-cycle for its clients. By way of mutual agreement when these circuits are employed in a system, the client is provided a non-exclusive use license totally unencumbered as part of the development contract.

Definition starts when our clients provide us with a general description of their power source requirements. Since efficacy relates directly to the dynamic output or load characteristics of our client’s proprietary electrode devices, we encourage clients to start with us early in the process.

We offer lab-based proof-of-concept services and concurrent engineering models of the client’s device in order to establish impedance ranges, crest factors, and waveform requirements. At this time we offer other consulting services related to the construction of client’s device to help ensure proper materials are employed in order to increase gap impedances and reduce leakage currents or to avoid the effects of capacitive coupling as well as RFI/EMI issues.

As a matter of policy we do not submit written bids until the client engages with us in preparation of a definition package defining both the product and the project. This includes a hierarchical system diagram that references various functional circuits mentioned above.

This “Definition” package includes the following items:

- Industrial Design Renderings - fully detailed
- Fully Detailed FRD - including defaults
- Hierarchical Systems Diagram
- Detailed Development Plan - by milestone deliveries
- Gantt Timeline - including projected client reviews
- Draft Acceptance Criteria - for each performance issue
- Pay-Out Schedule - based on milestone deliveries
- Draft PDA (Product Development Agreement)
- Formal Quotation
The definition package is the property of the client upon completion. It can be used to ensure all quotes received are comparing apples to apples when viewing competitive quotes.

The Red arrows in front of each document listed as part of the definition package can be inserted directly into the DHF (Design History File) later. Obviously, Industrial Designs offered by various outsource contractors are going to affect cost differently and as a result some designs are going to be more cost effective than others. Design always drives cost for tooling.

After an R-NDA is executed Tektran will prepare a private ftp site for the client where sample documents will be uploaded for client review. This is a password protected site.

The ftp site will include examples of our Industrial Designs, preliminary process directives further explaining our design protocols and even some defensive planning tips with respect to EMI/RFI issues - helpful to our design partners when engaging collaborative projects.

When a hierarchical system diagram is completed, we will upload Tech Briefs, detailing various functional circuits referenced on that diagram.

**Design & Development Process**

Our PDA (Product Development Agreement) includes the preceding Definition Package documents and are referenced by Control No. and Rev-code as Exhibits in that draft Agreement. The PDA follows our development and production protocols and is clearly written. It is also written to allow the client to issue a Stop Order to deal with problems on their end or the option to take the DMRs at the completion of development and manage their own production.

If you require an RF/High Frequency electro medical power source, the benefit of dealing with Tektran is we have developed scores of ESU related functional circuits, making much of the development process a matter of configuring a system from circuits that are already proven in prior system configurations.

The FDA requires that a Design History File (DHF) be maintained and provides the following guidelines for its content:

- **General - FDA Filings & Notices**
- **Development Plan - without cost detail**
- **Design Input - detailed FRD**
- **Design Output**
- **Review - acceptance criteria (by mutual agreement)**
- **Verification**
- **Validation**
- **Change Control**

All the items above marked in Red are taken directly from the Definition work product on the preceding page.

A record of all Design Output is maintained based on the specifications in the FRD. Output reports and/or samples are included in each milestone performance issue, delivered to the client for formal review and acceptance. Unless there are prerequisites, or the client instructs us to do otherwise, we normally move forward on as many parallel timeline projects that we can while the client is in review mode.

The V&V (Verification & Validation) matrix is typically based upon a checklist provided by the client’s third party compliance/certification body. A list of qualified third party compliance testing certificates are listed on the FDA web site.

There is a recognized FDA Guideline document used when preparing a 510(k) for an Electrosurgical generator or Ablation power source. We normally provide assistance to our client in drafting their FDA 510(k) filing. This includes assisting our clients in identifying predicate devices for SE (Substantially Event) filing when possible.

One of the main concerns the FDA has regarding Design Controls is the system for Change Control. Tektran has documented policies and procedures for processing ECOs, during design and production or for sustained engineering once production has begun. System changes can be very pervasive and even affect spare parts and sub-assembly configurations for after sales service.

Development includes three build stages:

- **First Article Prototype**
- **Protocol Validation Run - re-validate build & process docs**
- **Production**

Typically, clients will order 2 or 3 First Article Prototypes for systems V&V. Rev. A as a matter of policy begins when the first article working prototypes are completed. We do a “consigned” build with our EMS partner for boards only and assemble these First Article Prototypes in our lab to study assembly issues to include those issues in our “build” and “line” process documentation for follow-up production.

**Production Planning**

Protocol Validation Runs usually involve 25 units or more. During this pre-production phase we work closely with our EMS partner to learn where production can be improved and to
re-validate and ready all documentation for Transfer to Production.

A checklist of all related device and package labeling is also validated during this period. This includes IFU (Instructions for Use) and IFM (Instruction for Maintenance) manuals and other container documentation.

Often custom Test Fixtures are required, along with related TCP (Test & Calibration Procedures) to support the build and test process. In addition to such test fixture our EMS partner has automated boundary and J-Tag test equipment as well as optical scanners to quickly spot assembly errors.

Without at least one short lot run or Protocol Validation lot, the client risks the chance that the DMR (Device Master Records) or “build” documents may not be fully validated. Validation lots are also a time everyone in the supply chain can study their costs and take steps to reduce it. All parties involved are well aware that cost is related to volume.

By now, after reading about the entire product realization cycle, you begin to realize system development and production is far from a typical vendor relationship - it is seldom successful if not viewed as a quasi-partnership.

The Build

Before even the protocol validation run begins, we work together with our EMS partner to prepare a Production Plan. In addition to the document describing the parts, fabricated items, and assemblies, “line” process documents must be prepared. This is a formal plan that typically includes flow charts, assembly instructions, in-process inspection documents, Process Travelers, TCPs (Tests & Calibration Procedures), test Certs, and a checklist for preparing container contents and labeling by lot and unit serial number.

Line documents will vary depending on machine protocols and where production takes place. When special assembly techniques are required we will prepare Personnel Training & Certification documents. Our EMS maintains a classroom facility with DVD players and other equipment.

The TCPs include a list of test equipment traceable to NIST and a log of any test gear used for each lot run is recorded by model, serial number, or property tag number. Tektran consigns whatever test instruments required for the TCP to our EMS partner for their value-added test assignments.

A copy of all validated DMR (Device Master Records), including the “line” process documents are placed in a locking file set and delivered to a secure location within our EMS partner’s facility. That file set also includes labeled folders for the ongoing maintenance of DHRs (Device History Records).

Serial tags are prepared in advance for each lot run and consigned to our EMS partner along with a full complement of container documentation and labels or pre-serialized box content labels for both unit cartons and master cartons. This includes pre-serialized DHR (Device History Record) forms filed in a locked FDA(c)GMP file set prepped in advance by Tektran.

Using master cartons protects the integrity of unit cartons and allows us to ship units so the client can run a functional checklist test, reset Mains tap switches, insert international power cords, or add “starter kit” items to unit cartons prior to shipment to distributors or end-users as well as apply whatever additional labeling they require.

Tektran also has a documented protocol for collecting consigned file sets and returning them to its storage area for safe keeping for the life of the product or turn them over to the client upon request.

In-Warranty Service

Tektran normally provides its clients with up to (18) months warranty against defects in material or workmanship when awarded production rights beyond protocol validation runs. The terms for in-warranty service are included in our Design Portfolio CD, along with samples of our service forms.

Everything up to this point is enforced in the MLA (Manufacturing License Agreement), Tektran has executed with its EMS partner. Any and all material and equipment is consigned to our EMS under bailment until returned to Tektran or shipped to our clients. Tektran prefers to handle in-warranty service itself initially to learn first hand what corrective action is required. All changes during production are subject to client approval in advance.

Although, our clients are responsible for Med-Watch Reports, we maintain a corresponding MDR complaint file and log with trend data, subject to FDA inspection.

Out-Warranty Service

We also offer out-of-warranty service agreements to service your distributors or end-user. All communication with distributors or end-users are through our clients.