

Delphi Consulting Group

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Consulting Terms and Fees

Consulting services from Delphi Consulting Group (DCG) provided to clients under the following conditions and terms:

DCG personnel act as an independent consultant and not as an agent or employee of client i.e. IRS 1099. DCG shall be responsible for all taxes as an independent consultant.

DCG shall have no authority to bind client or incur obligations on behalf of client except when specified in a signed and dated contract agreement.

A signed and dated agreement of confidentiality between client and DCG shall precede any services.

All produced document are provided without copyright in Word (doc or docx), WordPerfect X4, and/or Open Office3 (doc or odt) file formats in Windows or Linux OS as selected by client. All supplied Federal Government data/documents provided "as is."

Detailed Breakdown of Fee Structure

Fees determined by quotation, fixed price, or person-day basis. Each client's regulatory needs are unique and thus require a complete review for an acceptable and proper Statement of Work (SoW) and Cost Quotation.

Established DCG hourly fee rates for services are as follows:

Regulatory/Submission work..... \$ 85.00 US

The above rates include normal office supplies, computer services, and shipping costs. All non-labor services billed without markup. Time billed in half-hour increments. DCG utilizes UTBMS billing codes. Document Copies, binders, and other expenses required when submission are sent to the FDA are billed at cost.

Estimated costs of common tasks

The following provided for budget estimates only. Each task requires an analysis to determine true DCG costs or estimated costs. Fixed price contract possible for common devices. All estimates shown are based on **no** travel. DCG utilizes the Internet to reduce travel to zero. After 30 years of submission experience DCG does not believe any travel is required to provide successful FDA release to market for any device.

Traditional 510(k) submissions, less testing, FDA and/or 3rd party review and validation costs.

Non-powered disposable device.....	\$ 5,000 to >\$ 10,500
Non-powered disposable device – sterilized.....	\$ 6,000 to >\$ 12,500
Non-powered implanted	\$ 7,000 to \$ A/R
Powered, non-wireless, w/o sterilization needs.....	\$ 6,000 to >\$ 12,500
Powered, wireless with/without sterilization needs.....	\$ 6,500 to >\$ 12,500

FDA or Third Party Review Fees

The FDA review fee schedule for fiscal year 2008 (Oct 2009 through Sep 2010) is:

510(k) Standard Fee.....	\$ 4,007
510(k) Small Business.....	\$ 2,004
513g Fee Standard.....	\$ 2,940
513g Small Business.....	\$ 1,470

Note: To received the Small Business Fee rate company must provide financial data to the FDA. With Standard Fee rate, this is not required.

Common Third Party review fees range between \$ 4,700 to >\$ 10,000.

Testing Costs - Typical

The following provided for **budget estimates only**. Each task requires an analysis to determine true testing costs or estimated costs. Fixed price contract possible for common devices from some testing companies.

Safety Testing electro/mechanical device – range between \$ 4,500 to \$ 9,000
EMI Testing – range between \$ 7,000 and \$ 15,000
Bio and Toxic – range between \$ 8,000 to >\$ 25,000
Sterilization Validation – range between \$ 4,000 to >\$ 9,000
Bench Testing – range between \$ 3,000 to A/R, very device dependent

Disclaimer

DCG and contracted firms will make good faith effort to meet all current and established regulations, laws, and guidelines in the production of supplied documentation and counsel. However, the interpretation of regulations often is subject to individual understanding, thus, DCG cannot guarantee that another agency or person will reach the same conclusions in each case.

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Each DCG contract shall contain a client cancellation cost. This cancellation cost shall be based on the complexity of the task.