Delphi Consulting Group (DCG)
11874 South Evelyn Circle
Houston, Texas 77071-3404
harvey.knauss@gmail.com
Tel 832-675-9281
Fax 713-723-0786
www.delphiconsulting.com

DCG is a boutique US FDA regulatory assistance firm serving worldwide medical device manufactures with product release in the US and Canadian market. With the following services; Good Manufacturing Practices [GMPs],[1] documentation, acting as US Agent,[2] and other FDA and Health Canada interface requirements. Our small size and low overhead costs allow us to provide prompt response to needs, with equitable overall costs. DCG's client base is worldwide. DCG works to make all tasks and task costs as transparent as possible.

Consulting Terms and Fees

Consulting services from Delphi Consulting Group (DCG) are 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, dated agreement of confidentially and consulting agreement between client and DCG shall precede any services.
- All produced document are provided without copyright in Word (doc or docx), WordPerfect, and/or TextMaker file formats in Windows or Linux OS as selected by client. All files stored in Dropbox folders with 'Share.' All supplied Federal Government data/documents provided "as is."

Detailed Breakdown of DCG 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 proper Consulting Agreement and Statement of Work (SoW) and Cost Quotation.

Task Description	Hourly Billing Rate	Comments
General Regulatory/Submissions	$85.00 US	All general regulatory tasks. Used as a billing rate for Not to Exceed Cost Quotations. Time billed in fifteen minute increments.

[1] Good Manufacturing Practices are custom edited for a given business, contact DCG for costs.
[2] US Agent costs are determined by the number of products covered.

Task Description	Hourly Billing Rate	Comments
E-mails requesting information and require research	$85.00 US	Billing maybe accumulated for the month or billed as running time.
Teleconferences when DCG is the host	$85.00 US	Billed as true running time in one minute increments. DCG utilizes Skype, Zoom, or Talky for host.
Teleconferences as participant only	$45.00 US	Billed as true running time in one minute increments.
Not to Exceed Cost Quotations	As quoted	Applies only to submissions with established FDA process does not consider extra tasks.
Client Retainer Contracts	As quoted	This style of contract can be advantageous for clients with defined needs on going.

The above rates include normal office supplies and computer services. All non-labor services billed without mark up. Time billed in quarter-hour increments. Document Copies, binders, FedEx, and other expenses required when submission are sent to the FDA are billed at cost.

Estimated costs of common tasks

The following is provided for budget estimates only. Each task requires an analysis to determine true DCG costs or estimated costs. Fixed price, turnkey contract(s) 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. There are reasons why FDA Meetings should be of the Teleconference type rather then 'face-to-face.' [3] This is a real cost saving to client.

Costs - Typical - Safety Testing and Submission

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 [General]

DCG Does not conduct any testing.
The below Estimated costs are based on
past costs from Certified Testing Companies.

Safety Testing electro/mechanical device – ranges between $ 8,500 to $ 20,000
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

DCG Estimated Submission Preparation and Monitoring of FDA Review Billing costs

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

[3] Call DCG (+832-675-9281) for a full explanation of this.

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 >$ 15,500

FDA User Fees for F/Y 2019

The Fees for Fiscal Year 2019 (October 1, 2018 through September 30, 2019) are as follows:

Application Type	Standard Fee	Small Business Fee±
510(k) ±±	$10,953	$2,738
513(g)	$4,349	$2,175
De Novo Classification	$96,644	$24,161
PMA, PDP, PMR, BLA	$322,147	$89,537
Panel-track supplement	$241,610	$60,403
180-day supplement	$48,322	$12,081
Real-time supplement	$22,550	$5,638
BLA efficacy supplement	$322,147	$80,537
Annual Report	$11,275	$2,819
30-day notice	$5,154	$2,577

± For small businesses with an approved Small Business Decision (SBD).
±± Note: all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the use fee. However, 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer do not have a user fee. However, Third Party has a fee, often much higher than the FDA fee. Note: DCG's observation has not found any real advantage

---

with the use of Third Party review and/or any time saved.

Area in light blue is for Premarket Approval (PMA) submissions.
Small businesses may apply for a (SBD) with gross receipts of sales of $ 30 Million or less are eligible to have the fee waived on their first PMA, PDP, PMR, or BLA. Note: SBD applications require release of company and/or investors tax information.

Annual Establishment Registration fee is $4,884. A true physical address must be provided. There are no waivers or reductions for small establishments, businesses, or groups – all establishments must pay the same establishment registration fee.

Web page for filing for Small Business Certification: https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm615142.htm

Small Business Certification is free and requires an annual renew.

Note: All **User Fees** must be paid in full one or two days > before a submission is sent in to the FDA.

Disclaimer

DCG and contracted firms will make a good-faith effort to meet all current and established regulations, laws, and guidelines for 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.

All submissions, reports and letters issued by Delphi Consulting Group are for the exclusive use of the client/sponsor to whom they addressed. Documents may not be reproduced except in their entirety. No quotation from reports or use of the company's name is permitted except as expressly authorized by Delphi Consulting Group or the document's client owner in writing. Delphi Consulting Group or the document's client owner makes no warranties if any kind, express or implied. Delphi Consulting Group or the document's client owner expressly states that the use of this data is the sole responsibility of the user. Delphi Consulting Group or the document's client owner shall not be liable for any incidental or consequential damages resulting from the application or use of this data.

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